ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 141 and 142

[WH-FRL-_____]

RIN 2040-_____

National Primary Drinking Water Regulations: Stage 2 Disinfectants and Disinfection Byproducts Rule (Stage 2 DBPR)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: In this document, EPA is proposing maximum contaminant level goals (MCLGs) for chloroform, monochloroacetic acid (MCAA) and trichloroacetic acid (TCAA); National Primary Drinking Water Regulations (NPDWRs) which consist of maximum contaminant levels (MCLs) and monitoring, reporting, and public notification requirements for total trihalomethanes (TTHM - a sum of chloroform, bromodichloromethane, dibromochloromethane, and bromoform) and haloacetic acids (HAA5 - a sum of mono-, di-, and trichloroacetic acids and mono- and dibromoacetic acids); and revisions to the reduced monitoring requirements for bromate. This document includes the best available technologies (BATs) upon which the MCLs are based. This set of regulations proposed today is known as the Stage 2 Disinfectants and Disinfection Byproducts Rule (Stage 2 DBPR). EPA believes the implementation of the Stage 2 DBPR will reduce peak and average levels of disinfection byproducts (DBPs) in drinking water supplies which will result in reduced risk from reproductive and developmental health effects and cancer.

The Stage 2 DBPR applies to public water systems (PWS) that are community water systems (CWSs) and nontransient noncommunity water systems (NTNCWs) that add a primary or residual disinfectant other than ultraviolet light or deliver water that has been treated with a primary or residual disinfectant other than ultraviolet light.

DATES: The Agency requests comments on today's proposal. Comments must be received or post-marked by midnight _____. Comments received after this date may not be considered in decision making on the proposed rule. The incorporation by reference of certain publications listed in today's rule is approved by the Director of the Federal Register as of [insert date 60 days after publication of FR document].

ADDRESSES: Please submit an original and three copies of your written comments and enclosures (including references) on today's proposed rule to the W-00-26 Stage 2 DBPR Comment Clerk: Water Docket (MC 4101), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460. Hand deliveries should be delivered to: EPA's Water Docket at 401 M Street, S.W., Washington, DC 20460.

Those who comment and want EPA to acknowledge receipt of their comments must enclose a self-addressed stamped envelope. No facsimiles (faxes) will be accepted. Comments may also be submitted electronically to ow-docket@epa.gov. For additional information on submitting electronic comments see Supplementary Information Section.

Public comments on today's proposal, other major supporting documents, and a copy of the index to the public docket for this rulemaking are available for review at EPA's Office of

Water Docket: 401 M Street, S.W., Rm. EB57, Washington, DC 20460 from 9:00 am to 4:00 pm, Eastern Time, Monday through Friday, excluding legal holidays. For access to docket materials or to schedule an appointment, please call (202) 260-3027. Some docket materials are online as indicated in the reference section.

FOR FURTHER INFORMATION, CONTACT: For general information contact, the Safe Drinking Water Hotline, Telephone (800) 426-4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding Federal holidays, from 9:00 am to 5:30 pm Eastern Time. For technical inquiries, contact Tom Grubbs, Office of Ground Water and Drinking Water (MC 4607), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460; telephone (202) 260-7270. For regulatory inquiries, contact Jennifer McLain at the same address; telephone (202) 260-0431. For Regional contacts see Supplementary Information.

SUPPLEMENTARY INFORMATION: Entities potentially regulated by the Stage 2 DBPR are community and nontransient noncommunity water systems that add a primary or residual disinfectant other than ultraviolet light or deliver water that has been treated with a primary or residual disinfectant other than ultraviolet light. Regulated categories and entities include:

Category	Examples of Regulated Entities
Industry	Community and nontransient noncommunity water systems that add a primary or residual disinfectant other than ultraviolet light or deliver water that has been treated with a primary or residual disinfectant other than ultraviolet light.

Category	Examples of Regulated Entities
State, Local, Tribal, or Federal Governments	Same as above

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by the Stage 2 DBPR. This table lists the types of entities that EPA is now aware could potentially be regulated by this rule. Other types of entities not listed in this table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the definition of "public water system" in §141.2 and the section entitled "coverage" (§141.3) of the Code of Federal Regulations and applicability criteria in §141.10xx of today's proposal. If you have questions regarding the applicability of the Stage 2 DBPR to a particular entity, contact one of the persons listed in the preceding section entitled "FOR FURTHER INFORMATION CONTACT" or the Regional contacts below.

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Submitting Comments

Send an original and three copies of your comments and enclosures (including references) to W-00-26 Comment Clerk, Water Docket (MC 4101), U.S. Environmental

Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460. Comments must be received or post-marked by midnight _____.

To ensure that EPA can read, understand and therefore properly respond to comments, the Agency would prefer that commenters cite, where possible, the paragraph(s) or sections in the proposed rule or supporting documents to which each comment refers. Commenters should use a separate paragraph for each issue discussed.

Electronic Comments

Comments may also be submitted electronically to ow-docket@epa.gov. Electronic comments must be submitted as an ASCII, WP5.1, WP6.1 or WP8 file avoiding the use of special characters and form of encryption. Electronic comments must be identified by the docket number W-00-26. Comments and data will also be accepted on disks in WP 5.1, 6.1, 8 or ASCII file format. Electronic comments on this document may be filed online at many Federal Depository Libraries.

The record for this rulemaking has been established under docket number W-00-26, and includes supporting documentation as well as printed, paper versions of electronic comments. The record is available for inspection from 9 a.m. to 4 p.m., Monday through Friday, excluding legal holidays at the Water Docket, Rm. EB 57, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460. For access to docket materials, please call (202) 260-3027 to schedule an appointment. Some docket materials are online as indicated in the reference section.

Abbreviations used in this Document

AIP	Agreement in Principle
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
ATSDR	Agency for Toxic Substances and Disease Registry
AWWA:	American Water Works Association
AWWARF	American Water Works Association Research Foundation
AWWSCo:	American Water Works Service Company
BAT:	Best available technology
BCAA:	Bromochloroacetic acid
BDCAA:	Bromodichloroacetic acid
BDCM:	Bromodichloromethane
CCR	Consumer Confidence Report
CDBP	Chlorination disinfection byproducts
CDC:	Centers for Disease Control and Prevention
CHF	Chlorohydroxyfuranone
C.I.:	Confidence intervals
CMA:	Chemicals Manufacturers Association
CWS:	Community water system
DBAA:	Dibromoacetic acid
DBCAA:	Dibromochloroacetic acid
DBCM:	Dibromochloromethane

DBP:	Disinfection byproduct
DBPR:	Disinfection Byproducts Rule
DCAA:	Dichloroacetic acid
DOC:	Dissolved organic carbon
DOD	Department of Defense
DS Average	Distribution system average
DS High	Distribution system high
DS Maximum	Distribution system maximum
DWSRF:	Drinking Water State Revolving Fund
EA:	Economic analysis
EC:	Enhanced coagulation
EDA	Ethylenediamine
EPA:	United States Environmental Protection Agency
ESWTR:	Enhanced Surface Water Treatment Rule
EHC:	Environmental health criteria
FACA:	Federal Advisory Committee Act
FBRR:	Filter Backwash Recycling Rule
FLR	Full liter resorption
GAC10:	Granular activated carbon with ten minute empty bed contact time and 180 day reactivation frequency
GAC20:	Granular activated carbon with twenty minute empty bed contact time and 180 day reactivation frequency

GC/ECD	Gas chromatography using electron capture detection
GWR:	Groundwater Rule
GWSS	Ground Water Supply Survey
GWUDI	Ground water under the direct influence of surface water
HAA5:	Haloacetic acids (five)(sum of chloroacetic acid, dichloroacetic acid, trichloroacetic acid, bromoacetic acid, and dibromoacetic acid)
HAN:	Haloacetonitriles
IC	Ion chromatograph
ICP/MS	Ion chromatograph–coupled to an inductively coupled plasma mass spectrometer
ICR:	Information Collection Rule
ICRSS	Information Collection Rule Supplemental Surveys
ICR:	Information Collection Rule
IDSE:	Initial distribution system evaluation
ILSI:	International Life Sciences Institute
IESTWR:	Interim Enhanced Surface Water Treatment Rule
IPCS:	International Programme on Chemical Safety
IRFA	Initial Regulatory Flexibility Analysis
IRIS:	EPA's Integrated Risk Information System
LH	Luteinizing hormone
LOAEL:	Lowest observed adverse effect level
LRAA:	Locational running annual average
LT1ESTWR:	Long-Term 1 Enhanced Surface Water Treatment Rule

LT2ESTWR: Long-Term 2 Enhanced Surface Water Treatment Rule

MBAA: Monobromoacetic acid

MCAA: Monochloroacetic acid

MCL: Maximum contaminant level

MCLG: Maximum contaminant level goal

M-DBP: Microbial and disinfection byproducts

mg/L: Milligrams per liter

MRL: Minimum reporting level

MRDL: Maximum residual disinfectant level

MRDLG: Maximum residual disinfectant level goal

MTBE Methyl tertiary butyl ether

NDIR Nondispersive infrared detection

NDMA N-nitrosodimethylamine

NDWAC: National Drinking Water Advisory Council

NF Nanofiltration

NOAEL: No Observed Adverse Effect Level

NODA: Notice of data availability

NPDWR: National primary drinking water regulation

NRWA National Rural Water Association

NTNCWS: Nontransient noncommunity water system

NTP: National Toxicology Program

NTTAA: National Technology Transfer and Advancement Act

NTU:	Nephelometric turbidity unit
ODA	*o*-dianisidine dihydrochloride
OMB:	Office of Management and Budget
OR	Odds ratios
OSTP	Office of Science and Technology Policy
PAR:	Population attributable risk
PE:	Performance evaluation
PWS:	Public water system
QC:	Quality control
RAA:	Running annual average
RFA:	Regulatory Flexibility Act
RfD:	Reference dose
RIA:	Regulatory impact analysis
RSC:	Relative source contribution
RSD	Relative standard deviation
SAB:	Science Advisory Board
SAC	Selective anion concentration
SBAR:	Small Business Advisory Review
SBREFA:	Small Business Regulatory Enforcement Fairness Act
SDS	Simulated distribution system
SDWA:	Safe Drinking Water Act, or the "Act," as amended in 1996
SER:	Small Entity Representative

SRR Standardized rate ratio

SUVA:Specific ultraviolet absorbance

SWAT Surface Water Analytical Tool

SWTR: Surface Water Treatment Rule

tAME tertiary amyl methyl ether

TBAA: Tribromoacetic acid

TC: Total coliforms

TCAA:Trichloroacetic acid

TCR: Total Coliform Rule

TDI Tolerable daily intake

THM Total trihalomethane

TOC: Total organic carbon

TOX: Total organic halides

TTHM: Total trihalomethanes (sum of chloroform, bromodichloromethane, dibromochloromethane, and bromoform)

TNCWS: Transient noncommunity water systems

TWG: Technical work group

UMRA: Unfunded Mandates Reform Act

URTH:Unreasonable risk to health

USACEHR US Army Center for Environmental Health Research

UV/VIS ultraviolet/visible

VOCs Volatile Organic Compounds

WIDB: Water Industry Data Base

WTP: Willingness to pay

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A. Why is EPA proposing the Stage 2 DBPR?

Disinfectants are an essential element of drinking water treatment because of the barrier they provide against harmful waterborne microbial pathogens. However, disinfectants react with naturally occurring materials in the water to form unintended byproducts which may pose health risks. Today, EPA is proposing the Stage 2 Disinfection Byproducts Rule (DBPR) as well as the accompanying Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) (USEPA, 2002) to further mitigate the potential health hazards of DBPs and microbial contaminants, especially *Cryptosporidium*. Both epidemiology and toxicology studies have raised concern regarding potential health effects from DBPs. Studies of human populations exposed to DBPs and disinfected drinking water and studies of animals exposed to high doses of individual DBPs have both indicated potential carcinogenic, developmental, and/or reproductive risks. The Microbial and Disinfection Byproducts (M-DBP) Advisory Committee, convened in March 1997 under the Federal Advisory Committee Act (FACA) (henceforth cited as the Advisory Committee or the Committee) and reassembled in March 1999, was reconvened to advise EPA on the development of the Stage 2 microbial and disinfection byproduct regulations. The Advisory Committee was composed of representatives from States, local governments, water utilities, equipment manufacturers, consumer protection groups, and environmental and public health organizations. After a thorough examination of available health effects, occurrence, technology, and cost data, the Advisory Committee unanimously agreed with the need for the Stage 2 DBPR to reduce potential risks from DBPs, especially reproductive and developmental risks and recommended a specific course of action to address the risk (USEPA, 2000i).

In December 1998, EPA promulgated the Stage 1 DBPR which primarily focused on reducing chronic risk, such as cancer (USEPA, 1998c). The Stage 1 DBPR set a number of standards that utilities must comply with based on a running annual average (RAA). Under such a standard, systems average all samples collected in their distribution system over a one-year period. This permits some locations within a distribution system to have higher DBPs than others. The system is not required to reduce these high levels as long as the average is below the MCL. In some situations the population served by certain portions of the distribution system may receive water that regularly exceeds the MCL.

Today, EPA is proposing DBP standards based on a locational running annual average (LRAA) compliance calculation. An LRAA differs from a RAA in that each sample point must be in compliance with the standard as an annual average. Thus, utilities will be compelled to address occurrence points in their distribution system that have consistently high levels because the effects of these peaks on compliance will no longer be dampened by averaging across the entire distribution system. The intent of this regulation is to target high DBP levels and reduce the variability of exposure for people served by different points of the distribution system. As a result of LRAA compliance, average DBP levels will decrease and peak DBP levels will likely appreciably decrease.

Today's proposed rule also includes a requirement for systems to perform an initial distribution system evaluation (IDSE) which will refocus their sampling plan on points within the distribution system that better represent the highest concentrations of TTHM and HAA5. The decrease in DBP levels anticipated to result from the transition from a RAA to an LRAA proposed rule will be augmented by the IDSE. These changes in compliance determination and

sampling plans will moderate exposure inequities across the distribution system which will provide benefits from reduced health risks.

Section 1412 (b)(2)(C) of the Safe Drinking Water Act (SDWA) requires EPA to promulgate a Stage 2 Disinfectants/Disinfection Byproducts Rule 18 months after promulgation of LT1ESWTR. Consistent with statutory requirements for risk balancing, EPA will finalize the LT2ESWTR concurrent with the Stage 2 DBPR, to ensure parallel protection from microbial and DBP risks.

B. What are the health risks associated with DBPs?

EPA's main mission is the protection of human health and the environment. When carrying out this mission, EPA bases its decisions on the best available science. However, EPA must often make regulatory decisions with less than complete information and with uncertainties in the available information. EPA believes that consistent with the public health protection goals of the SDWA, it is appropriate and prudent to err on the side of public health protection when there are indications that exposure to a contaminant may present risks to public health, rather than take no action until risks are unequivocally proven. Such is the case with the Stage 2 DBPR. The best available science indicates that cancer, reproductive, and developmental risks may be associated with exposure to DBPs and disinfected drinking water.

As in the Stage 1 DBPR, the assessment of public health risks from DBPs currently relies on inherently difficult analyses of incomplete empirical data. Epidemiology studies are limited by difficulties in measuring exposure, controlling for confounding factors, and eliminating bias. Likewise, uncertainty is involved in using the results of high dose animal toxicological studies of a few of the numerous byproducts that occur in disinfected drinking water to estimate the risk to

humans from exposure to low doses of these and other byproducts. In addition, such studies of individual byproducts cannot characterize the entire mixture of disinfection byproducts in drinking water. While recognizing these uncertainties, EPA believes that the weight of evidence represented by the available epidemiology and toxicology studies on disinfected water and DBPs continues to support a concern for health risk and a protective public health approach to regulation of DBPs.

A fundamental component in assessing the risk for a contaminant is the number of people that may be exposed to it. In this case, there is a very large United States population potentially exposed to DBPs through drinking water. Approximately 241 million people are served by PWSs that apply a disinfectant to water in order to provide protection against microbial contaminants (USEPA, 2001c). While these disinfectants are very effective in controlling many microorganisms, they also form DBPs. Because of the large number of people exposed to DBPs through activities such as drinking water and showering, there is a substantial concern for any risks associated with DBPs that may impact public health.

Since the discovery of chlorination byproducts in drinking water in 1974, numerous toxicological studies have been conducted. Results from these studies have shown several DBPs (e.g., bromodichloromethane, bromoform, dichloroacetic acid and bromate) to be carcinogenic in laboratory animals. Some DBPs (e.g., chlorite, bromodichloromethane (BDCM), and certain haloacetic acids) have also been shown to cause adverse reproductive or developmental effects in laboratory animals. Although many of these animal studies have been conducted at high doses, EPA believes the studies provide evidence that DBPs present a potential public health risk that needs to be addressed.

A number of epidemiology studies have been conducted to investigate the relationship between exposure to disinfected water and adverse effects like cancer or developmental and reproductive outcomes. While EPA cannot conclude there is a causal link between exposure to chlorinated surface water and cancer, some epidemiology studies studies have suggested an association, albeit small, between bladder, rectal, and colon cancer and long term exposure to chlorinated surface water. Although there are fewer published epidemiology studies that have been conducted to evaluate the possible relationship between drinking water and reproductive and developmental effects, recent studies report increased risks for low birth weight, term low birth weight, birth defects, miscarriage, and stillbirth to women exposed to chlorinated surface water and elevated concentrations of TTHM. As with cancer, although EPA cannot conclude at this time that there is a causal link between exposure to chlorinated water or DBPs and reproductive and developmental effects, there is a troubling indication of an association. Furthermore, reproductive and developmental effects may occur after short durations of exposure.

While EPA recognizes there are uncertainties in the information on the health effects from the DBPs and the levels at which they occur, the Agency believes the weight of evidence presented by the available epidemiological studies on chlorinated drinking water and toxicological studies on individual DBPs support EPA's concern about a potential health hazard. We conclude that this concern warrants regulatory action at this time to reduce DBP levels in drinking water. EPA believes that reducing exposure to average and peak levels of DBPs in the distribution system, by means of changing the basis of compliance to an LRAA and revising

compliance sample points, is prudent and necessary to protect public health and meet the requirements of the SDWA.

In conclusion, because of the large number of people exposed to DBPs and the different potential health risks (e.g., cancer and adverse reproductive and developmental effects) that may result from this exposure, EPA believes the Stage 2 DBPR is needed to further reduce potential health effects from DBPs, beyond those controlled for by the 1998 Stage 1 DBPR.

C. How is EPA proposing to regulate DBPs?

Today, EPA is proposing a phased TTHM and HAA5 MCL implementation strategy and parallel rule compliance with the LT2ESWTR at the recommendation of the M-DBP Advisory Committee and in order to comply with statutory requirements for risk balancing (section 1412(b)(5) of the Act). EPA is proposing that initially, systems comply with transitional MCLs of 0.120 mg/L TTHM and 0.100 mg/L HAA5 as LRAAs as well as maintain compliance with the Stage 1 DBPR MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as RAAs. Subsequently, systems will comply with long-term MCLs of 0.080 mg/L for TTHM and 0.060 mg/L for HAA5 as an LRAA. In addition, in order to identify optimal sample locations for long-term compliance monitoring, systems will be required to perform an initial distribution system evaluation (IDSE) in which systems will either monitor for TTHM and HAA5 for one year at a number of sample points throughout their distribution system or submit system-specific data that provides equivalent or better information on sample site selection.

1. Initial distribution system evaluation

The specifics of the proposed IDSE requirements are discussed in sections V.E., V.F., and V.G. of this preamble and in §141.10xx of today's rule. IDSEs are intended to indicate new

compliance monitoring sites that better represent the highest concentrations of TTHM and HAA5 in a system's distribution system.

Systems conducting IDSE monitoring will monitor for one year on a regular schedule that is determined by source water type and system size (see Section V.F.). In lieu of distribution system monitoring, systems may perform a site-specific study based on historical monitoring studies or data as long as the alternative study provides comparable or superior information for selection of new monitoring sites that target high TTHM and HAA5 levels.

States may waive the IDSE requirement for certain systems that serve populations fewer than 500. In addition, systems that certify to their state that all properly analyzed samples taken in the two years prior to the start of the IDSE, under an appropriate sampling plan, were $\leq$ 0.040 mg/L TTHM and 0.030 mg/L HAA5 are not required to conduct the IDSE. EPA guidance for systems and States on IDSEs is discussed in section I.F. of this preamble.

2. Locational running annual average MCLs

The specifics of the proposed MCL requirements are discussed in sections V.C., V.F., and V.G. of this preamble and in §141.10xx of today's rule. TTHM and HAA5 MCL compliance will each be determined as an LRAA. Due to the Stage 2 M-DBP Advisory Committee recommendation for parallel rule compliance schedules for the Stage 2 DBPR and the LT2ESWTR and in order to comply with statutory requirements for risk balancing, EPA is proposing that systems comply with the Stage 2 DBPR MCL in two phases. These were named Phase 1 and Phase 2 in the M-DBP Agreement in Principle (AIP); because of confusion with other similarly named drinking water regulations, EPA has designated these as Stage 2A and Stage 2B. In Stage 2A, three years after rule promulgation, all systems must comply with short-

term MCLs of 0.120 mg/L TTHM and 0.100 mg/L HAA5 as an LRAA based on approved Stage 1 DBPR sampling plans and must also continue to comply with the Stage 1 DBPR MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as a RAA. In Stage 2B, systems must comply with long-term MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as an LRAA based on new sampling sites identified under the IDSE. Large and medium systems must comply with Stage 2B long-term MCLs six years after rule promulgation. Small systems required to do *Cryptosporidium* monitoring under the LT2ESWTR must comply with Stage 2B long-term MCLs 8.5 years after rule promulgation. All other small systems (i.e., those that do not need to conduct *Cryptosporidium* monitoring and therefore do not need the additional time) must comply 7.5 years after rule promulgation. An additional 2 year extension is available for all systems from their State (in the case of an individual system) if it is determined that the system requires additional time for capital improvements.

In accordance with the Advisory Committee's recommendation, EPA is proposing that all wholesale and consecutive systems must comply with provisions of the Stage 2 DBPR on the same schedule required of the wholesale or consecutive system serving the largest population in the combined distribution system. This will ensure that the consumers of the drinking water sold to the public by these water systems are protected.

D. Why is EPA proposing a new MCLG for chloroform?

In December 1998, EPA promulgated the Stage 1 DBPR, (USEPA, 1998c) which included NPDWRs for a number of disinfectants and DBPs and an MCLG of zero for chloroform, a trihalomethane. The chloroform MCLG was challenged in court, and the U.S. Court of Appeals for the District of Columbia Circuit issued an order vacating the zero MCLG

(Chlorine Chemistry Council and Chemical Manufacturers Association v. EPA, No. 98-1627 (opinion filed March 31, 2000)) the Court remanded the case to the Agency noting that EPA had committed to a new rulemaking which would propose and finalized a non-zero MCLG for chloroform (Chlorine Chemistry Council and Chemical Manufacturers Association v. EPA, No. 98-1627 (opinion filed June 27, 2000)). On May 30, 2000, EPA (USEPA, 2000g) removed the MCLG for chloroform from its NPDWRs. No other provision of the Stage 1 DBPR was affected.

Today, EPA is proposing a chloroform MCLG of 0.070 mg/L based upon the best available peer reviewed science. As emphasized in the Stage 1 DBP final rule, the Agency continues to recognize the strength of the science in support of a nonlinear approach for estimating the carcinogenicity of chloroform. This science was affirmed by the Chloroform Risk Assessment Review Subcommittee of the EPA Science Advisory Board (SAB) Executive Committee which met on October 27-28, 1999 (USEPA, 2000h). The Subcommittee agreed that the nonlinear approach is most appropriate for the risk assessment of chloroform. Section V.A. further discusses the derivation of the chloroform MCLG.

E. What other requirements are included in this proposal?

1. DBP occurrence peaks

EPA believes that MCLs based on an LRAA, in combination with the IDSE, will reduce exposure peaks. However, since systems are allowed to average their compliance measurements over a one year period, even when a system is in compliance with an MCL as an LRAA, there will likely be occurrence levels that exceed the MCL. The Advisory Committee was concerned about the possible impact of periodic high DBP levels, even when a system is in compliance with

the LRAA. In order to enhance the benefits of this rule, the Advisory Committee recommended that as a part of the sanitary survey process, systems review peaks in TTHM and HAA5 occurrence that have occurred in their distribution system. Today, EPA is proposing this recommendation. A peak is defined as any individual sample level of 0.100 mg/L TTHM or 0.075 mg/L HAA5 (25% over the MCL). Public water systems are required to maintain a record of TTHM and HAA5 concentrations detected at each sample location. EPA is developing guidance for public water systems and states on how to conduct peak excursion evaluations, and how to reduce peak excursions of DBP levels through actions such as distribution system operational changes (Section I.F.).

2. Bromate reduced monitoring qualification

EPA proposes that ozone systems with a running annual average of bromate less than 0.0025 mg/L are eligible for reduced monitoring. This replaces reduced monitoring provisions based on source water bromide levels. EPA believes that basing reduced monitoring for bromate on low bromate levels will be more accurate than basing reduced monitoring on the bromate precursor bromide. This issue was not discussed by the Advisory Committee.

F. How will this proposed regulation protect public health?

Exposure to DBPs is so pervasive and the exposed population is so large that even small increases in risk are a concern. People are exposed to DBPs through activities such as drinking water and showering. Recent epidemiology studies have focused concern on reproductive and developmental outcomes. These studies are supported by the findings, in laboratory animals, that certain DBPs are reproductive/developmental toxins. EPA believes that the proposed Stage 2 DBPR will decrease risk to pregnant women and their fetuses. In addition, this regulation will

decrease cancer risk which has also been indicated by epidemiological and toxicological research.

The objective of the Stage 2 DBPR is to shift the MCL compliance calculation to target DBP peaks in the distribution system. EPA is proposing to change the method of calculating compliance for the TTHM and HAA5 MCLs to an LRAA, which will require systems to comply with the MCL as an annual average at each sample point. This change will in effect, reduce exposure variations across the distribution system so that the water quality received by people served by a particular section of the distribution system will be comparable to that received by people served by other sections. This change will also operate to decrease overall levels of DBPs in the distribution system as systems make technology changes to reduce DBP levels at sites in the distribution system that are out of compliance. The decrease in DBP levels anticipated to result from the transition from a RAA to an LRAA proposed rule will be augmented by the IDSE, which should yield monitoring programs that better detect peak levels in drinking water distribution systems. In order to ensure that systems are fairly capturing DBP levels in their distribution system, this proposal requires systems to monitor on a regular schedule. Systems will no longer be able to select a particular month for monitoring because of expected low DBP levels. This proposed rule also provides the opportunity for a system to monitor peak DBP levels in its distribution system, those that occur even while the system is in compliance, and discuss options for reducing those peaks with their State during the sanitary survey process.

These elements of today's proposal were consensus recommendations of the Stage 2 M-DBP Advisory Committee. In the process of developing the final recommendations, the

Committee discussed the ultimate public health objective of the Stage 2 DBPR. Some Committee members believed strongly that the epidemiological and toxicological evidence for reproductive and developmental health risks, although uncertain, warranted immediate and stringent DBP control. Other Committee members believed that due to the uncertainties in the data, only modest, if any, DBP control measures should be taken. All Committee members expressed concern for potential health risks to pregnant women and their fetuses from DBPs.

EPA believes that this proposal achieves an appropriate balance between the available science and the uncertainties. Although an LRAA will not remove all DBP occurrence peaks, this proposed regulation will ensure that DBP exposures across a utility's distribution system are more equitable and will achieve cancer and reproductive and developmental risk reduction benefits.

EPA also believes that today's proposal is an important step in addressing reproductive and developmental risks from DBPs. In the 1996 SDWA Amendments, Congress emphasized the importance of considering the effects of drinking water contaminants on subpopulations such as pregnant women and their fetuses that are "likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population" (section 1412(b)(3)(C)(i)(V)). Future research and public discussion will determine whether steps to further reduce exposure are warranted.

As systems make changes to comply with the Stage 2 DBPR, the average and peak levels of DBPs that people are exposed to will decrease. EPA believes that this decrease in DBPs will provide a benefit of decreased reproductive/developmental and cancer risk.

It is important to maintain a risk balance between DBP and microbial risks. The Advisory Committee considered the impact of DBP control on microbial protection when they recommended the MCLs in today's proposal. Today's proposal also contains provisions for parallel rule compliance with the LT2ESWTR. Simultaneous compliance was recommended by the Stage 2 M-DBP Advisory Committee so that systems would not compromise microbial protection while attempting to meet lower DBP levels. This requirement is consistent with statutory requirements to "minimize the overall risk of adverse health effects by balancing the risk from the contaminant and the risk from other contaminants, the concentrations of which may be affected by the use of a treatment technique or process that would be employed to attain the maximum contaminant level" (section 1412(b)(5)(B)(i)).

G. What guidance is EPA developing for systems and states for the implementation of the Stage 2 DBPR?

EPA is developing a number of guidance manuals that will be available to stakeholders and the public first for review in draft and then in final form. These are described below:

1. Stage 2 DBPR Distribution System Guidance Manual

This document will consist of two sections, the first of which will help systems conduct an IDSE. This section will advise systems and States on how to select appropriate IDSE monitoring months (e.g., selecting the peak historical month), identify sites for an IDSE monitoring program, select Stage 2 DBPR compliance monitoring sites based on their IDSE results, conduct studies of site specific data in lieu of monitoring, and determine system eligibility for IDSE exemptions. The second section will provide guidance to systems and States on how to recognize significant excursions of DBP levels, those that occur even when systems

are in full compliance with the enforceable MCL, and on how to conduct peak excursion evaluations. This section will also provide guidance on how to evaluate peaks in TTHM and HAA5 occurrence and how to reduce peak excursions of DBP levels through actions such as distribution system operational changes.

2. Small System Compliance Document

This document, which is required by SBREFA, will provide guidance to small systems and States on complying with the Stage 2 DBPR.

3. Consecutive System Guidance Manual

This document will provide guidance to consecutive systems and States on complying with the Stage 2 DBPR.

4. Addendum to the Stage 1 DBPR Simultaneous Compliance Guidance Manual

This addendum will address issues unique to the Stage 2 M-DBP rules that are not covered in the Stage 1 DBPR Simultaneous Compliance Guidance Manual. For example, how a system might consider UV in complying with both the LT2 and Stage 2 DBPR, while also maintaining compliance with existing disinfection requirements of the SWTR.

H. Will this proposed regulation apply to my water system?

Your drinking water system is subject to these requirements if it is a community or nontransient noncommunity water system that adds a primary or residual disinfectant other than ultraviolet light or delivers water that has been treated with a primary or residual disinfectant other than ultraviolet light.

II. Background

A. What is the statutory authority for the Stage 2 DBPR?

The SDWA, as amended in 1996, requires the EPA to promulgate a NPDWR and publish a MCLG for each contaminant the Administrator determines "may have an adverse effect on the health of persons," is "known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern," and for which "in the sole judgement of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems" (SDWA Section 1412 (b)(1)(A)). MCLGs, which are non-enforceable health goals, are to be set at a level at which "no known or anticipated adverse effect on the health of persons occur and which allows an adequate margin of safety" at the same time the NPDWR is published (Section 1412(b)(4) and 1412(a)(3)).

The Act also requires that at the same time EPA publishes a NPDWR and MCLG, it also must specify in the NPDWR a maximum contaminant level (MCL) which is as close to the MCLG as feasible (Sections 1412(b)(4) and 1401(1)(c)). EPA is authorized to promulgate a NPDWR "that requires the use of a treatment technique in lieu of establishing a MCL," if the Agency finds that "it is not economically or technologically feasible to ascertain the level of the contaminant"(Sections 1412(b)(7)(A) and 1401(1)(C)).

The Agency may also consider additional health risks from other contaminants and establish an MCL "at a level other than the feasible level, if the technology, treatment techniques, and other means used to determine the feasible level would result in an increase in the health risk from drinking water by– (i) increasing the concentration of other contaminants in drinking water; or (ii) interfering with the efficacy of drinking water treatment techniques or processes that are used to comply with other national primary drinking water regulations"

(Section 1412(b)(5)(A)). When establishing an MCL or treatment technique under this authority, "the level or levels or treatment techniques shall minimize the overall risk of adverse health effects by balancing the risk from the contaminant and the risk from other contaminants the concentrations of which may be affected by the use of a treatment technique or process that would be employed to attain the MCL or levels" (Section 1412(b)(5)(B)). Finally, in setting an MCL or treatment technique at these levels, "the combination of technology, treatment techniques, or other means required to meet the level or levels shall not be more stringent than is feasible" as defined in the statute (Sections 1412(b)(5)(B) and 1412(b)(4)(D)).

The Amendments also require EPA, when proposing a NPDWR that includes an MCL or treatment technique, to publish and seek public comment on an analysis of health risk reduction and cost impacts. This includes an analysis of quantifiable and nonquantifiable costs and health risk reduction benefits, incremental costs and benefits of each alternative considered, the effects of contaminants upon sensitive subpopulations (e.g., infants, children, pregnant women, the elderly, and individuals with a history of serious illness), increased risks including those from co-occurring contaminants, and other relevant factors. (Section 1412 (b)(3)(C)).

Finally, section 1412 (b)(2)(C) of the Act requires EPA to promulgate a Stage 2 Disinfectants and Disinfection Byproducts Rule 18 months after promulgation of LT1ESWTR. Consistent with statutory requirements for risk balancing (Section 1412(b)(6)), EPA will finalize the LT2ESWTR concurrent with the Stage 2 DBPR, to ensure parallel protection from microbial and DBP risks.

B. What is the regulatory history for the Stage 2 DBPR?

This section briefly describes the regulatory development of the Stage 2 DBPR and other relevant rule development processes and applicable existing regulations.

1. Initial regulatory requirements

On November 29, 1979 (44 FR 68624) (USEPA, 1979) EPA set an interim MCL for TTHMs of 0.10 milligrams per liter (mg/L) as an annual average. Compliance was defined on the basis of a running annual average of quarterly averages of all samples throughout the distribution system. The value for each sample was the sum of the measured concentrations of chloroform, bromodichloromethane (BDCM), dibromochloromethane (DBCM) and bromoform. This interim TTHM standard only applies to community water systems using surface water and/or ground water serving at least 10,000 people that add a disinfectant to the drinking water during any part of the treatment process. At their discretion, States could extend coverage to smaller PWSs; however, most States did not exercise this option.

Under the Surface Water Treatment Rule (SWTR) (54 FR 27486, June 29, 1989) (USEPA,1989a), EPA set maximum contaminant level goals (MCLGs) of zero for *Giardia lamblia*, viruses, and *Legionella*; and promulgated NPDWRs for all PWSs using surface water sources or ground water sources under the direct influence of surface water. The SWTR includes treatment technique requirements for filtered and unfiltered systems that are intended to protect against the adverse health effects of exposure to *Giardia lamblia*, viruses, and *Legionella*, as well as many other pathogenic organisms. Briefly, those requirements included: 1) maintenance of a disinfectant residual in the distribution system; 2) removal and/or inactivation of 3 logs (99.9%) for *Giardia* and 4 logs (99.99%) for viruses; 3) combined filter effluent performance of 5 nephelometric turbidity units (NTU) as a maximum and 0.5 NTU at

95th percentile monthly, based on 4-hour monitoring for treatment plants using conventional treatment or direct filtration (with separate standards for other filtration technologies); and 4) watershed protection and other requirements for unfiltered systems.

EPA promulgated the Total Coliform Rule (TCR), also on June 29, 1989 (54 FR 27544)(USEPA,1989b) to provide protection from microbial contamination in distribution systems of all types of public water supplies. The TCR established an MCLG of zero for total and fecal coliform bacteria, and an MCL based on the percentage of positive samples collected during a compliance period. Under the TCR, no more than 5 percent of distribution system samples collected in any month may contain coliform bacteria. The number of samples to be collected in a month is based on the number of people served by the system. The location and frequency of sampling is based on a system-specific sampling plan that provides representative coverage throughout the distribution system.

Total coliforms are a group of closely related bacteria that are generally free-living in the environment, but are also normally present in water contaminated with human and animal feces. They generally do not cause disease (there are, however, some exceptions). Specifically, coliforms are used as a screen for recent fecal contamination, as well as to determine the physical integrity of the drinking water distribution system against microbial intrusion and contamination from any source. The presence of total coliforms in drinking water indicates that the treatment system is not operating properly and/or that the distribution system is either fecally contaminated or vulnerable to fecal contamination.

Combined, the SWTR and the TCR are intended to address risks associated with microbial pathogens that might be found in source waters or associated with distribution systems.

2. Evaluation of health risks and identification of need for a staged M-DBP regulatory strategy

In 1992, prompted by concerns about health risk tradeoffs between disinfection byproducts and microbial pathogens, EPA initiated a negotiated rulemaking. The negotiators included representatives of State and local health and regulatory agencies, public water systems, elected officials, consumer groups and environmental groups. The Regulatory Negotiating Committee met from November 1992 through June 1993. Following months of intensive discussions and technical analyses, the Regulatory Negotiating Committee recommended the development of three sets of rules: an Information Collection Rule, or ICR (USEPA, 1996b), a two-staged approach for the DBPs (Stage 1 DBPR: USEPA, 1998c), and an "interim" Enhanced Surface Water Treatment Rule (IESWTR: USEPA, 1998d) and a "final" ESWTR that would apply to large and small Subpart H systems, respectively.

EPA's approach in developing the DBP rules, the IESWTR, and related microbial rules (collectively referred to as microbial and disinfection byproducts (M-DBP) rules) is discussed in the following section. The Agency promulgated the ICR in 1996 to collect data on pathogen and DBP treatment and occurrence in order to assess the extent and severity of risks during future rulemaking efforts. The ICR was part of a twofold approach adopted by the Agency to address critical data needs; first, requiring monitoring under the ICR, and secondly, developing and implementing a M-DBP Research Strategy to address additional research needs. The relationship of the ICR data to the M-DBP rules is discussed below. Section III (Public Health Risk) discusses relevant new information from the health effects research.

Congress affirmed this phased M-DBP rulemaking strategy in the 1996 SDWA Amendments by requiring that EPA develop these three sets of rules on a schedule that specifies simultaneous promulgation of rules governing microbial protection and DBPs.

3. First stage of M-DBP regulatory development

In March 1997, the Agency established the M-DBP Advisory Committee under FACA to collect, share, and analyze new information and data available since EPA proposed the Stage 1 DBPR and IESWTR in 1994, as well as to build consensus on the regulatory implications of the new information. The Committee consisted of 17 members representing EPA, State and local public health and regulatory agencies, local elected officials, drinking water suppliers, chemical and equipment manufacturers, and public interest groups.

The M-DBP Advisory Committee met five times in March through July 1997 to discuss issues related to the IESWTR and Stage 1 DBPR. Technical support for these discussions was provided by a Technical Work Group (TWG) established by the Committee at its first meeting in March 1997. The Committee's activities resulted in the collection, development, evaluation, and presentation of substantial new data and information related to key elements of both proposed rules. The Committee reached agreement on a number of major issues that were incorporated into the Stage 1 DBPR and the IESWTR.

The Stage 1 Disinfectants and Disinfection Byproducts Rule and Interim Enhanced Surface Water Treatment Rule, finalized in December 1998, were the first rules to be promulgated under the 1996 SDWA Amendments (USEPA 1998c and 1998d). The Stage 1 DBPR applies to all community and nontransient noncommunity water systems that add a chemical disinfectant to the water in any part of the drinking water treatment process. In

addition, transient noncommunity water systems that use chlorine dioxide must meet the chlorine dioxide maximum residual disinfectant level (MRDL) standard. Large (serve 10,000 or more people) subpart H systems (those using surface water or ground water under the direct influence of surface water) are required to comply with the Stage 1 DBPR and IESWTR in January 2002. Ground water systems and small (serve 9,999 or fewer people) subpart H systems must comply with the Stage 1 DBPR by January 2004.

The Stage 1 DBPR will reduce exposure to three disinfectants and many disinfection byproducts. The rule established maximum residual disinfectant level goals (MRDLGs) and enforceable MRDL standards for three chemical disinfectants – chlorine, chloramine and chlorine dioxide. It also established maximum contaminant level goals (MCLGs) and enforceable maximum contaminant level (MCL) standards for total trihalomethanes, five haloacetic acids, chlorite, and bromate. Water systems that use surface water or ground water under the direct influence of surface water (hereafter collectively referred to as surface water systems or as subpart H systems) and use conventional filtration treatment are required to remove specified percentages of organic materials, measured as total organic carbon (TOC), that may react with disinfectants to form DBPs. Removal will be achieved through a treatment technique (enhanced coagulation or enhanced softening) unless a system meets alternative compliance criteria.

EPA finalized the IESWTR at the same time as the Stage 1 DBPR to assure simultaneous compliance for large systems. In general, the IESWTR applies to all subpart H systems that serve at least 10,000 people. The purposes of the IESWTR are to: improve control of microbial pathogens in drinking water, including specifically the protozoan *Cryptosporidium*; and address

risk trade-offs with disinfection byproducts. Key provisions of the rule include: a maximum contaminant level goal of zero for *Cryptosporidium*; 2- log *Cryptosporidium* removal requirements for systems that filter; strengthened performance standards for combined filter effluent turbidity and individual filter turbidity levels for systems that use conventional or direct filtration; disinfection benchmark provisions to ensure continued levels of protection against pathogens while facilities take the necessary steps to comply with the new DBP standards; inclusion of *Cryptosporidium* in the definition of ground water under the direct influence of surface water (GWUDI) and in the watershed control requirements for unfiltered PWSs; requirement for covers on new finished water reservoirs; and sanitary surveys of all surface water systems, regardless of size.

4. Rules related to the first stage of M-DBP requirements

In 2001, EPA promulgated the Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR) and Filter Backwash Recycling Rule (FBRR) to increase protection of finished drinking water supplies from contamination by *Cryptosporidium* and other microbial pathogens (USEPA, 2001d,i,j). The LT1ESWTR applies to subpart H systems extending protection against *Cryptosporidium* and other disease-causing microbes to the subpart H systems that serve fewer than 10,000 people. Compliance dates coincide with those in the Stage 1 DBPR to assure simultaneous compliance for small systems. The provisions fall into the following three categories:

(1) Turbidity

- Conventional and direct filtration systems must comply with specific combined filter effluent turbidity requirements;

- Conventional and direct filtration systems must continuously monitor the turbidity of individual filters and comply with follow-up activities based on this monitoring;

(2) Disinfection Benchmarking

- Systems will be required to develop a disinfection profile unless they perform TTHM and HAA5 monitoring which demonstrates their disinfection byproduct levels are less than 80 percent of the maximum contaminant levels;
- If a system considers making a significant change to their disinfection practice they must develop a disinfection benchmark and consult with the State for approval prior to implementing the change;

(3) Other Requirements

- All systems must meet the requirements for achieving a 2-log removal of *Cryptosporidium*;
- Finished water reservoirs for which construction begins after the effective date of the rule must be covered; and
- Unfiltered systems must comply with updated watershed control requirements that add *Cryptosporidium* as a pathogen of concern.

The FBRR applies to all public water systems that:

- use surface water or ground water under the direct influence of surface water (GWUDI);
- utilize direct or conventional filtration processes; and

- recycle spent filter backwash water, sludge thickener supernatant, or liquids from dewatering processes.

The FBRR requires that recycled filter backwash water, sludge thickener supernatant, and liquids from dewatering processes must be returned to a location such that all processes of a system's conventional or direct filtration including coagulation, flocculation, sedimentation (conventional filtration only) and filtration, are employed. Systems may apply to the State for approval to recycle at an alternate location.

The FBRR also requires that systems notify the State in writing that they practice recycle. When notifying the State, systems must also provide the following information:

- A plant schematic showing the origin of all recycle flows, the hydraulic conveyance used to transport them, and the location where they are recycled back into the plant; and
- Typical recycle flow (gpm), highest observed plant flow experienced in the previous year (gpm), design flow for the treatment plant (gpm), and the State-approved operating capacity for the plant where the State has made such determinations.

Finally, systems must collect and maintain the following information for review by the State, which may, after evaluating the information, require a system to modify their recycle location or recycle practices:

- Copy of the recycle notification and information submitted to the State;
- List of all recycle flows and the frequency with which they are returned;

- Average and maximum backwash flow rate through the filters and the average and maximum duration of the filter backwash process in minutes;
- Typical filter run length and a written summary of how filter run length is determined (headloss, turbidity, time etc.);
- The type of treatment provided for the recycle flow; and
- Data on the physical dimensions of the equalization and/or treatment units, typical and maximum hydraulic loading rates, type of treatment chemicals used and average dose and frequency of use, and frequency at which solids are removed where such units are used.

The 1996 SDWA Amendments also require EPA to "promulgate criteria ... to determine whether disinfection shall be required as a treatment technique for any public water system served by ground water." EPA proposed the Ground Water Rule (GWR) on May 10, 2000 (USEPA 2000l), and expects to promulgate a final GWR by 2002. The proposed GWR is a targeted risk-based regulatory strategy for all ground water systems. The proposed requirements provide a meaningful opportunity to reduce public health risk associated with the consumption of waterborne pathogens from fecal contamination for a substantial number of people served by ground water sources.

The proposed strategy addresses risks through a multiple-barrier approach that relies on five major components: periodic sanitary surveys of ground water systems requiring the evaluation of eight elements and the identification of significant deficiencies; hydrogeologic assessments to identify wells sensitive to fecal contamination; source water monitoring for systems drawing from sensitive wells without treatment or with other indications of risk; a

requirement for correction of significant deficiencies and fecal contamination through the following actions:

- eliminate the source of contamination;
- correct the significant deficiency;
- provide an alternative source water, or provide a treatment which achieves at least 99.99 percent (4-log) inactivation or removal of viruses; and
- compliance monitoring to insure disinfection treatment is reliably operated where it is used.

EPA estimates that over 14,000 systems will take corrective action to address microbial contamination as a result of the GWR, and that almost 8,000 systems will select disinfection treatment as their corrective action.

5. Second stage of M-DBP regulatory development

As discussed above, EPA promulgated the ICR to collect water quality, occurrence, treatment, and engineering information necessary for evaluating the need for and extent of future M-DBP regulations. The ICR provided EPA and stakeholders with a significant new source of data on the national occurrence in drinking water of (1) source water quality parameters (2) disease-causing microorganisms, including *Cryptosporidium, Giardia,* and viruses, and (3) DBPs and their precursors. The ICR also provides engineering data on how PWSs currently control for such contaminants. This 18 month data-set is the most comprehensive data collection effort to provide occurrence of TTHMs, HAA5 and bromate, the DBPs addressed in today's rule, as well as relevant water quality parameters and treatment conditions influencing the formation of DBPs.

The ICR applied to large public water systems serving populations of at least 100,000; a more limited set of ICR requirements applied to ground water systems serving between 50,000 and 100,000 people. There were 296 PWSs operating 501 treatment plants involved with the extensive ICR data collection. Over an 18-month period beginning in July 1997, these PWSs collected monthly samples for microbial data as well as water quality parameters affecting DBP formation and quarterly samples for DBPs within the treatment plant and in the distribution system. In addition, PWSs provided operating data and a description of their treatment plant design. Surface water systems conducted monthly monitoring for bacteria, viruses, and protozoa. Finally, a subset of PWSs performed treatment studies, using either granular activated carbon (GAC) or membrane processes, to evaluate DBP precursor removal and control of DBPs. Monitoring for treatment study applicability began in September 1996 and treatment studies were completed by the summer of 1999. The ICR data supports the economic analyses for various regulatory options considered during development of today's proposed Stage 2 DBPR.

In March 1999, EPA reconvened the M-DBP Advisory Committee to develop recommendations on issues pertaining to the development of the Stage 2 DBPR and LT2ESWTR. The Committee consisted of 21 organizational members representing EPA, State and local public health and regulatory agencies, local elected officials, native american tribes, drinking water suppliers, chemical and equipment manufacturers, and public interest groups. Technical support for the Committee's discussions was provided by a TWG established by the group. The Committee's activities resulted in the collection, development, evaluation, and presentation of substantial new information related to key elements for both rules. This information included new data on pathogenicity, occurrence, and treatment of microbial

contaminants, specifically including *Cryptosporidium*, as well as new data on DBP health risks, exposure, and control.

The ICR was a significant source of this new information. The TWG used several other data sources to characterize DBP occurrence, influent water conditions and treatment at systems not included in the ICR data collection effort. The analysis focused on using this characterization to make predictions about the types of technnology selections these systems would make to comply with the proposed Stage 2 DBPR and a companion LT2ESWTR. The data that supported this analysis include:

1) a survey of 117 plants serving fewer than 10,000 people (National Rural Water Association Survey (NRWA Survey)); 2) data provided by various States; 3) the Water Utility Database which contains data on large and medium systems collected in a 1996 survey by the American Water Works Association; and 4) the ICR Supplemental Surveys (ICRSS). The ICRSS involved 127 treatment plants, including 40 small systems, and comprised one year of bimonthly sampling for *Cryptosporidium*, *Giardia* (small systems did not measure protozoa), and water quality parameters (including DBP precusors).

EPA and the TWG used a series of databases, developed to facilitate analysis of ICR data, to characterize DBP treatment and occurrence at the ICR systems. The ICR databases were integrated with a Surface Water Analytical Tool (SWAT) to predict the impact of potential standards for DBPs and/or pathogen reduction on shifts in treatment technologies among surface water systems and resulting DBP exposure profiles. Based on engineering analysis using cost estimation models and data supplied by equipment vendors, the TWG produced unit cost estimates for a number of potential regulatory compliance technologies. These technology unit

costs were used in conjunction with SWAT projections of technology shifts to make national cost estimates for regulatory options.

The ICR data also served as a basis for analysis of large ground water systems. However, there was no SWAT-equivalent model available to make predictions for ICR ground water systems nor for systems not included in the ICR monitoring effort. Therefore, the TWG relied on a delphi process, which involved the professional judgement of a group of technical experts, as the primary basis of the Stage 1 and Stage 2 treatment change and occurrence predictions for these systems. This analysis is described in further detail in Section VII (Economic Analysis) of this Federal Register notice.

EPA, in consultation with nationally recognized experts in the field of statistics, evaluated ICR and ICRSS data to generate estimates of the national occurrence distribution of *Cryptosporidium*. Occurrence distributions were coupled with data on the infectivity of different strains of *Cryptosporidium* and assumptions for the removal efficiency of treatment plants to make projections of the possible risks associated with *Cryptosporidium* in drinking water. In considering risks associated with DBPs, the Committee reviewed available toxicological and epidemiological data from a number of studies on reproductive and developmental health effects (e.g., early term miscarriages), as well as cancer.

Despite the evaluation of a large amount of data, the Committee recognized that uncertainty remains in a number of areas regarding the precise nature and magnitude of risk associated with DBPs and pathogens in drinking water. In light of this uncertainty, the Committee recommended a series of balanced steps to address the greatest health concerns,

taking into careful consideration the analyses described above, including costs and potential impacts on public water systems.

In regard to DBPs, the Committee recommended a two phase approach to provide further control of concentration peaks in the distribution system. In Stage 2A, systems will continue to meet maximum contaminant levels (MCLs) established by the Stage 1 DBPR for TTHM and five haloacetic acids (HAA5) of 0.080 and 0.060 mg/L, respectively, with compliance based on a running annual average (RAA). In addition, Stage 2A would add new MCLs of 0.120 and 0.100 mg/L for TTHM and HAA5, respectively, with compliance based on a locational running annual average (LRAA). Under an LRAA standard, the annual average at each monitoring point must not exceed the MCL. This compares with the RAA established by the Stage 1 DBPR in which compliance is determined by averaging across all monitoring points. All Stage 2A monitoring will be conducted at Stage 1 DBPR sites. Stage 2B will consist of maintaining MCLs of 0.080 mg/L for TTHM and 0.060 mg/L for HAA5 but compliance with these MCLs will be based on the LRAA. Under Stage 2B, monitoring will be conducted at new sites determined from an initial distribution system evaluation (IDSE) designed to select site-specific optimal sample points for capturing DBP peaks.

The two phase approach recommended by the Committee for the Stage 2 DBPR will provide an initial level of protection from DBP peaks under Stage 2A. Systems will then make decisions regarding the potentially more significant treatment changes necessary to comply with Stage 2B during the same time period as they evaluate options to comply with the LT2ESWTR. This approach is consistent with the Committee's support for simultaneous compliance for the Stage 2 M-DBP rules and the statutory objectives for balancing microbial and DBP risks.

With regard to microbial pathogens, the Committee recognized that some systems with poor quality source waters may need to provide additional protection against *Cryptosporidium*. The Committee recommended a 'Microbial Framework' approach which involves assignment of systems into different risk categories (or bins) based on the results of source water *Cryptosporidium* monitoring. Additional treatment requirements depend on the bin to which the system is assigned. Systems may choose technologies to comply with additional treatment requirements from a 'toolbox' of options. The Committee also made recommendations for unfiltered systems and uncovered finished water reservoirs. These recommendations are addressed in the proposed LT2ESWTR, also published in today's Federal Register.

In September 2000 the Committee signed the Agreement in Principle– a full statement of the consensus recommendations of the group. The agreement was published by EPA in a December 29, 2000 Federal Register notice (65 FR 83015) and is included as an Appendix to this notice. The Agreement is divided into Parts A & B. The recommendations in each part stand alone and are independent of one another. The entire Committee reached consensus on Part A, which contains provisions that directly apply to today's proposed Stage 2 DBPR and LT2ESWTR (also contained in today's Federal Register). The full Committee, with the exception of the NRWA, agreed to Part B, which has recommendations for future activities by USEPA in the areas of distribution systems and microbial water quality criteria. Key components of the Agreement are summarized as follows:

Part A

Stage 2 DBPR

- Long term MCLs for total trihalomethanes (TTHM) and five haloacetic acids (HAA5) will remain at 0.080 and 0.060 mg/L, respectively.
- Compliance with MCLs for TTHM and HAA5 will be based on the locational running annual average (LRAA), in two separate phases of the rule.
- In Phase 1 (Stage 2A) of the rule, systems must comply with TTHM and HAA5 MCLs of 0.080 and 0.060 mg/L calculated as a RAA, and 0.120 and 0.100 mg/L calculated as a LRAA at each sample location.
- In Phase 2 (Stage 2B), compliance with TTHM and HAA5 MCLs of 0.080 and 0.060 mg/L is calculated as a LRAA for each of the new monitoring locations identified in an Initial Distribution System Evaluation (IDSE).
- Systems will carry out an IDSE to select new compliance monitoring sites that more accurately describe high TTHM and HAA5 levels. The studies will be based either on system-specific monitoring or other system-specific data that provide equivalent or better information on site selection.
- MCL for bromate will remain at 0.010 mg/L calculated as an RAA.

LT2ESWTR

- Additional treatment requirements for *Cryptosporidium* will be based on the results of source water monitoring.
- Systems that are required to provide additional treatment may choose technologies from a 'toolbox' of options.

- The monitoring burden for small systems will be reduced through the use of indicators to determine which systems must monitor for *Cryptosporidium*.
- Systems will conduct future monitoring to determine if source water quality has changed following completion of the initial monitoring.
- Unfiltered systems will provide at least 2-logs of *Cryptosporidium* inactivation, and unfiltered systems will meet overall inactivation requirements with a minimum of two disinfectants.
- Systems will cover all uncovered finished water reservoirs unless the reservoir effluent is treated to achieve 4-logs of virus inactivation or the State/Primacy Agency determines that existing risk mitigation is adequate.
- USEPA will develop guidance and criteria to facilitate the use of UV light for compliance with drinking water disinfection requirements.

Part B:

- Beginning in January, 2001, as part of the 6-year review of the Total Coliform Rule, USEPA will, working with stakeholders, initiate a process to address distribution system requirements related to significant health risks.
- The Committee recommends that EPA develop a national water quality criteria under the Clean Water Act for microbial pathogens for stream segments designated by States/Tribes for drinking water use.

These recommendations reflect the Committee's emphasis on targeted, risk-based rulemaking. They incorporate substantial initial monitoring to identify systems with the highest potential risk. Additional treatment steps are required only where systems exceed specified

locational average DBP concentrations or source water *Cryptosporidium* occurrence levels. In addition, the recommendations address risks from *Cryptosporidium* in unfiltered systems, as well as longstanding concerns over risks from uncovered finished water reservoirs. They also facilitate the use of nontraditional and potentially low cost treatment technologies like UV disinfection.

C. How were stakeholders involved in developing the Stage 2 DBPR?

1. Federal advisory committee process

As discussed above, EPA met with the Stage 2 M-DBP Advisory Committee which was made up of organizational members (parties) named by EPA (See USEPA, 2000j for a list of Committee members). All Advisory Committee meetings were open to the members of the public. There was also an opportunity for public comment at each meeting.

The Stage 2 M-DBP Advisory Committee considered both the strengths and limitations of new M-DBP information, as well as the related technical and policy issues involved in developing a Stage 2 DBPR and a LT2ESWTR under the Safe Drinking Water Act. Based on these considerations, the Committee recommended that EPA base applicable sections of Stage 2 DBPR and LT2ESWTR proposals on elements of the Committee's Agreement in Principle. These elements represent the consensus of the parties after consideration of available information and related technical and policy issues.

2. Small system outreach - SBREFA process

EPA received valuable input from small system operators as part of an Agency outreach initiative under the Small Business Regulatory Enforcement Fairness Act (SBREFA). EPA conducted three outreach conference calls from Washington, DC to solicit feedback and

information from Small Entity Representatives (SERs) on issues regarding Stage 2 DBPR impacts on small systems. These three outreach calls were designed to provide SERs with extensive background information, discuss specifics of the Stage 2 M-DBP rules, and receive feedback from the SERs. The first call was held on January 28, 2000. EPA presented an overview of SBREFA, the Safe Drinking Water Act as amended in 1996, and recent M-DBP drinking water regulations such as the Stage 1 DBPR and IESWTR as well as the then proposed LT1ESWTR and FBRR. In addition, preliminary issues and schedules for the Stage 2 M-DBP rules were discussed. The second meeting was held on February 25, 2000. EPA presented an overview of the EPA regulatory development process and background on the development of the Stage 2 M-DBP Rules which included health risks, issues/options identified by the FACA, and small system DBP and microbial occurrence data. At the third meeting on April 7, 2000, EPA presented cost estimates and impact analyses for selected regulatory options and requested written comments from the SERs. In addition, EPA presented SERs with schedules for the FACA and SBREFA processes. These three outreach calls were extremely useful and generated a wide range of information, issues, and technical input from SERs. A complete set of SER outreach documents and comments is available from the Water Docket in Washington, DC.

A number of the SERs that participated in the outreach process were invited to provide comment to the Small Business Advisory Review (SBAR) Panel, the final step in the SBREFA process. See Section VII for more information on the SBAR panel and the SBREFA process. The Agency utilized the feedback received during these three outreach meetings and during the SBAR panel process in developing today's proposed rule. EPA also mailed a draft version of the preamble for today's proposed rule to the SERs.

3. Other outreach Processes

In addition to the Federal Advisory Committee and SBREFA outreach processes, EPA has participated in several other outreach forums, including meetings of State and Tribal officials as well as EPA sponsored meetings with States and public water systems, in order to obtain input on draft proposal components.

Consistent with the intent of Executive Orders 13132 and 13084 and the Agency's policy to promote communications between EPA and State and local governments and tribal governments, the Agency has engaged the input of these groups on the draft proposed Stage 2 DBPR. Section VIII of today's Federal Register notice details several EPA Stage 2 DBPR outreach activities.

The Agency also held two meetings to discuss consecutive system issues relevant to the proposal (February 22-23, 2001 in Denver, CO. and March 28, 2001 in Washington, D.C.). Representatives from States, EPA Regions and public water systems participated in the discussions. Section V describes EPA's analysis of consecutive system issues, comments and input received during these sessions, and how the proposed requirements will apply to consecutive systems.

III. Public Health Risk

A. Reproductive and developmental epidemiology

The following sections briefly discuss reproductive and developmental epidemiology information received and analyzed since the December 1998 Stage 1 DBPR. This proposal presents some conclusions of these studies and reports, as well as implications for the Stage 2 DBPR.

EPA has evaluated recently published epidemiology studies examining the relationship between exposure to contaminants in chlorinated surface water and adverse reproductive and developmental outcomes. EPA also considered a critical review of the epidemiologic literature by Reif et al. (2000). Based on this evaluation, EPA believes that the reproductive and developmental epidemiology data contributes to the weight of evidence evaluation on the potential risks from exposure to chlorinated drinking water. Associations have been reported between exposure to chlorinated drinking water and a number of reproductive outcomes and developmental anomalies. However, currently available published studies are insufficient to establish a causal relationship between exposure to chlorinated drinking water and reproductive and developmental effects, furthermore they are not suitable for quantitative risk assessment.

1. Background

In 1993, an expert panel of scientists was convened by the International Life Sciences Institute (ILSI) to review the available human studies for developmental and reproductive outcomes and to provide research recommendations (USEPA/ILSI, 1993). The expert panel concluded that the epidemiologic results should be considered preliminary given that the research was at a very early stage (USEPA/ILSI, 1993; Reif et al., 1996).

Another expert panel, convened in 1997 to review the epidemiology studies published since 1993, concluded that the results of several studies suggested that an increased relative risk of certain adverse outcomes may be associated with the type of water source, disinfection practice, or THM levels (USEPA, 1997). The panel emphasized, however, that most relative risks are moderate or small and were found in studies with limitations in design or conduct.

EPA discussed several reproductive epidemiology studies in the proposed Stage 1 DBPR and associated Notices of Data Availability (NODAs) (USEPA, 1994b, 1997, 1998e). At the time of the final Stage 1 DBPR, EPA determined that the evidence on the association between exposure to chlorinated waters and adverse reproductive and developmental effects was inconclusive (USEPA, 1998f). However, EPA believed that the epidemiology studies contributed to the overall weight of evidence that exposure to DBPs poses a potential health effects risk as indicated by the Waller et al. (1998) study, conducted in California, that reported an association between miscarriage and exposure to THMs in drinking water.

2. New studies since the Stage 1 DBPR

Six epidemiology reports have been published since the 1998 Stage 1 DBPR and are summarized in this section. Epidemiology studies often report results as odds ratios (OR). The odds ratio is defined as the odds of exposed persons developing the disease compared to the odds of non-exposed persons developing the disease. If the exposure is not related to the disease, the odds ratio will equal 1. If the exposure is positively related to the disease, the odds ratio will be greater than 1. It is also important to consider the variability inherent in the estimate, which is reflected in the confidence interval. The confidence interval represents the range within which the true magnitude of effect lies with a certain degree of assurance. When the confidence interval around the OR includes 1, the association between disease and exposure is not considered statistically significant (Hennekes and Buring, 1987).

Exposure assessments in epidemiology studies are difficult. The exposure to chlorinated water with organic compounds is a complex mixture of a large number of agents with potential to cause adverse effects. The varying composition of the DBP mixture in the study locales may

contribute to the discrepancies identified in the existing database. Using TTHMs as a surrogate exposure may not necessarily reflect levels of brominated -THMs in some of these epidemiological studies. Based on studies in experimental animals and recent findings in humans, concentrations of specific brominated byproducts such as BDCM may be of critical importance for certain outcomes. Therefore, regional differences in the composition of the mixture may account for the disparate results reported by various authors.

a. Gallagher et al. 1998

Gallagher et al. (1998) conducted a retrospective cohort study in Colorado to examine the relationship between TTHM exposure during the third trimester of pregnancy to low birth weight (#5 pounds, 8 ounces), low birth weight at term ($37 weeks of gestation and #5 pounds, 8 ounces) and preterm delivery (<37 weeks of gestation). Estimates of TTHM concentration at maternal residence were based on TTHM data routinely collected by utilities from the distribution system that was adjusted to account for within-system spatial variability with a GIS based modeling technique.

Compared to the reference group (women exposed to #20 Fg/L estimated TTHM), women exposed to water containing $61 Fg/L TTHM had an increased risk for having a baby with low birth weight (OR = 2.1, 95% confidence interval of (1.0-4.8) and for low birth weight at term (OR = 5.9, 95% confidence interval (2.0-17.0) (the wide confidence intervals for low birth weight at term reflect the small number of births (n = 6) in the exposed category)). No association was reported between exposure to TTHM and preterm delivery (OR = 1.0. 95% confidence interval (0.3 - 2.8).

b. Dodds et al. 1999

Dodds et al. (1999) conducted a retrospective cohort study in the Canadian province of Nova Scotia to examine the relation between the level of TTHM and low birth weight (<2,500 gm), very low birth weight (<1,500 gm), preterm delivery (<37 weeks of gestation), small for gestational age (bottom one-tenth of the weight distribution among Canadian live births for each week of gestation for each sex), stillbirth (birth of nonliving fetus weighing 500 gm or more), and congenital anomalies (which included neural tube defects, cleft lip and palate, major cardiac defects, and choromosomal abnormalities). The study population consisted of 50,755 women residing in an area with municipal surface water. These women had a singleton birth in Nova Scotia between 1988 and 1995, or a pregnancy termination for a major fetal anomaly. The authors used linear regression to estimate the concentration of TTHM by month from quarterly sampling data within the distribution system of each public water facility.

The investigators found an elevated risk for stillbirth for average TTHM levels during pregnancy of 100 Fg/l or greater (OR = 1.66; 95% confidence interval 1.09-2.52) compared to the referent group of women exposed to TTHM levels of 0-49 Fg/l. Because of relatively high TTHM levels in Nova Scotia, the referent group contained women exposed to higher concentrations than typically used. The authors also observed an elevated prevalence of chromosomal abnormalities (adjusted prevalence ratio = 1.38; 95% confidence interval 0.73-2.59 for women exposed to TTHM levels of 100 Fg/l or greater) but there was no evidence of a dose-response. The investigators found little evidence of an association between TTHM level and outcomes related to fetal weight, gestational age, preterm delivery, or congenital defects.

c. King et al. 2000

King et al. (2000) used the Dodds et al. (1999) Nova Scotia study cohort to evaluate the relationship between the level of TTHMs and specific THMs in public water supplies and risk for stillbirth. Individual exposures were assigned by linking mother's residence at the time of delivery to the levels of specific THMs monitored in public water supplies.

The investigators found an association between risk for still birth and BDCM in drinking water at exposures $20 Fg/l (adjusted relative risk = 1.98; 95% confidence interval 1.23-3.49) compared to < 5 μg/L. An association between risk for still birth and chloroform in drinking water at exposure levels $ 100 Fg/L was also noted (Adjusted OR=1.56, 95% confidence interval 1.04-2.34). When analyzed as a continuous variable, BDCM in drinking water was associated with a 29% increase in risk for stillbirth for each 10 μg/L increase in concentration. TTHM was associated with a 5% increase in risk for each 10 Fg/L increase in concentration, consistent with the finding that BDCM in drinking water was the strongest predictor of risk for stillbirth in this study.

d. Magnus et al. 1999

Magnus et al. (1999) conducted a "semi-individual" ecologic study in Norway to examine the relationship between birth defects and water chlorination practice and color (used as an indicator for natural organic matter and DBPs). Exposure was assessed by linking the national waterwork registry with the national birth registry (1993-1995; 141,077 children). The authors reported that DBP concentrations in Norway were generally low (mean concentration of 9.4 Fg/l for TTHM and 14.6 Fg/l for HAAs). In a comparison between exposed (high color; chlorination) and reference groups (low color; no chlorination), the adjusted OR was 1.14 (95%

confidence interval 0.99-1.31) for any malformation, 1.26 (95% confidence interval 0.61-2.62) for neural tube defects and 1.99 (95% confidence interval 1.10-3.57) for urinary tract defects. Elevated risks were not observed for major cardiac defects, respiratory defects, or oral cleft defects.

e. Källén and Robert 2000

Källén and Robert (2000) conducted a cross-sectional population-based ecologic study in Sweden to examine the relationship between water disinfection practices and birth defects. The authors compared birth outcomes recorded in the Swedish national registry for women living in municipalities where the water supply was disinfected with chlorine (sodium hypochlorite) or chlorine dioxide or was untreated. Three years of data were analyzed and included approximately 74,300 births in referent areas, 15,400 in areas using chlorine dioxide and 24,700 in areas using sodium hypochlorite. Statistically significant associations with chlorination were found for pre-term delivery, low birth weight, short body length and small head circumference. These associations were not observed in communities which treated water with chlorine dioxide. No data on concentrations of DBPs in Swedish water supplies was provided.

f. Yang et al. 2000

Yang et al. (2000) conducted a cross-sectional population-based ecologic study in Taiwan to examine relationship between water disinfection practices and birth defects. Birth outcomes in 14 municipalities where chlorinated water was supplied to over 90 percent of the residents were compared to 14 non-chlorinating municipalities. Two years of singleton birth data (1994-1996) were analyzed for 18,025 women. Pre-term delivery (<37 weeks) occurred more often in residents of municipalities that treated water with chlorination (OR=1.34, 95% CI

1.15-1.56). No statistically significant associations were found for chlorination and birth weight or the percent term low birth weight. No THM concentration data were provided.

3. Reviews of the reproductive and developmental epidemiology literature

a. Nieuwenhuijsen et al. 2000

Nieuwenhuijsen et al. (2000) reviewed the toxicological and epidemiological literature and evaluated the potential risk of chlorination DBPs on human reproductive health. The authors conclude that although the evidence suggests small risks which are difficult to interpret, the large numbers of people exposed to chlorinated water supplies means that the number of people exposed and potentially at risk for adverse reproductive effects can be quite large. The authors point to exposure assessment as the main limitation of epidemiological studies and emphasize the public health benefits of chlorination in terms of microbiological safety.

b. WHO 2000

The International Programme on Chemical Safety (IPCS) published an evaluation of Disinfectants and DBPs in its Environmental Health Criteria (EHC) Monograph series (WHO, 2000). The EHC monograph contains the collective views of an international group of experts (Task Group). It is intended to provide a critical review on the effects on human health of disinfectants and DBPs and to assist national and international authorities in making risk assessments and subsequent risk management decisions. The monograph evaluates the chemistry, toxicology, and epidemiology of disinfectants and DBPs and provides conclusions on risk.

The report concludes that "(t)he existing epidemiological data are insufficient to allow the importance of the observed associations of chlorinated drinking-water or THMs and adverse

pregnancy outcomes to be assessed" (WHO, 2000). The Task Group encourages additional studies to determine the significance of the studies that have suggested increased risks.

c. Reif et al. 2000

In efforts to oversee a comprehensive update of the health risk information on THMs and other chlorination disinfection by-products (CDBP) and to develop recommendations for controlling risks, the CDBP Task Group, established by Health Canada, commissioned the report "Reproductive and Developmental Effects of Disinfection By-Products" by Dr. John Reif and colleagues from Colorado State University. Reif et al. (2000) completed a critical review of the epidemiology literature pertaining to reproductive and developmental effects of exposure to disinfection byproducts in drinking water. The review included 16 peer reviewed scientific manuscripts and published reports, of which ten were previously discussed in the Stage 1 DBPR. Reif et al. (2000) evaluated associations between DBP exposure and outcomes grouped as effects on (1) fetal growth (birth weight [as a continuous variable]; low birth weight [<2500 grams]; very low birth weight [<1500 grams]; preterm delivery [<37 weeks of gestation] and intrauterine growth retardation [or small for gestational age]); (2) fetal viability (spontaneous abortion and stillbirth) and (3) risk for fetal malformations (all malformations, oral cleft defects, major cardiac defects, neural tube defects, and chromosomal abnormalities).

The authors found mixed epidemiologic evidence for an association with DBPs and effects on fetal growth. Studies using TTHM concentrations (quantitative exposure assessment) reached differing conclusions. Some studies found weak but statistically significant associations (Gallagher et al., 1998; Bove et al., 1992 and 1995) but two studies found no association (Dodds et al., 1999; and Savitz et al. 1995). Studies with qualitative exposure assessment designs were

similarly variable in their findings (Kanitz et al., 1996; Källén and Robert, 1999; Jaakola et al., 1999; Yang et al., 2000).

For effects on fetal viability, Reif et al. (2000) reported that evidence for an increased risk of spontaneous abortion and stillbirth associated with DBPs exists, but is uncertain. Increased rates of spontaneous abortions associated with THM levels were reported by Waller et al. (1998). In addition, Aschengrau et al. (1989) reported a doubling of risk for exposure to treated surface water compared to ground and mixed water. Although Savitz et al. (1995) found an association with high levels of THMs, no relationship with dose or water source was observed. An increased risk of stillbirth was associated with TTHM and BDCM exposure (Dodds, et al., 1999; King, et al., 2000). Aschengrau et al. (1993) found an association between stillbirth and the use of a chlorinated vs. chloraminated water systems. In another set of studies, a weak association was found between risk of stillbirth and drinking water from surface water systems, but little evidence was found for an association with TTHM at 80 Fg/L (Bove et al., 1992, 1995). Thus the data show mixed results.

Reif et al. (2000) found that the literature to date for congenital anomalies provides an inconsistent pattern of association and a lack of agreement with specific anomalies across the relatively few studies that have explored these outcomes. The authors concede that an assessment of congenital anomalies is difficult due to the small number of cases available for evaluation and possible selection bias due to elective terminations of pregnancy.

Reif et al. (2000) explored the epidemiology literature for dose-response relationships. They did not find a dose-response pattern of increasing risk with increasing concentration of

TTHM but they did observe a general trend of small increases in reproductive/developmental risk for concentrations of TTHM greater than 100 μg/L.

Epidemiologists use population attributable risk (PAR) to quantify the fraction of disease burden in a population (e.g., bladder cancer) that could be eliminated if the exposure (e.g., chlorinated drinking water) was absent. PAR provides a perspective on the potential magnitude of risks associated with various exposures under the assumption of causality. The results of a population attributable risk (PAR) analysis, completed by Reif et al. (2000) , indicate that an important reduction in disease occurrence would be obtained by eliminating not only TTHM exposure levels above 80 μg/L but also levels between 60 μg/L and 80 μg/L. The authors note that this conclusion is tentative because many of the 95% confidence intervals were very wide and included 1.0.

Reif et al. (2000) provide several possible explanations for the discrepancies and inconsistencies among the epidemiologic studies: (1) substantial differences existed between methods of exposure assessment and, in some cases, definition of the outcome, (2) referent (comparison) groups varied across studies, (3) the composition of DBP mixtures may have varied across locales and studies and (4) other classes of DBPs may be the causal agents and THMs may have served as an exposure surrogate. Exposure misclassification in the studies may either hide a true effect or, in rare circumstances, create an artificial effect.

Reif et al. (2000) conclude that the weight of evidence from the epidemiological studies suggest that DBPs are likely to be reproductive toxicants in humans under appropriate exposure conditions. They observe that DBP toxicological data from animal studies provides biological plausibility for the effects observed in epidemiologic studies. Although the authors recognize

that the data are primarily at the stage of hazard identification (i.e., dose-response models cannot be developed from existing studies), they conclude that measures aimed at reducing the concentrations of byproducts could have a positive impact on public health.

4. Summary of key observations

EPA has evaluated reproductive and developmental epidemiology data published to date. Based on this evaluation, EPA believes that the epidemiology data provide important information that contributes to the weight of evidence evaluation on the potential risks from exposure to chlorinated drinking water. Although EPA finds the data insufficient for quantitative risk assessment, the Agency believes that the indication of an association between exposure to disinfected drinking water and reproductive and developmental birth defects is a cause for concern. EPA believes that the science, albeit uncertain, supports regulatory changes that target peak DBP exposures.

5. EPA's research program

As noted in the 1998 Stage 1 DBPR, EPA has an epidemiology research program that continues to examine the relationship between exposure to DBPs and adverse developmental and reproductive effects. EPA is supporting several studies using improved study designs to provide better information for characterizing potential risks. The studies include: a reanalysis of the Waller et al. (1998) study using improved exposure data; an ongoing prospective pregnancy study in California to which information on DBP levels from selected drinking water utilities is being added; a new study of miscarriage in North Carolina, Tennessee and Texas that is co-funded with American Water Works Association Research Foundation (AWWARF) and studies

of birth defects conducted in conjunction with the Centers for Disease Control (CDC), Centers for Birth Defects Research and Prevention, in locations throughout the U.S.

6. Request for comment

The EPA requests comment on the conclusions of the Reif et al. report (2000) and EPA conclusions drawn from the new epidemiologic information summarized in this section. EPA also requests comment on the information's potential impact on the regulatory provisions for the final Stage 2 DBPR. EPA solicits any additional epidemiologic data on the reproductive or developmental effects from DBPs that need to be considered for the final Stage 2 DBPR.

B. Cancer epidemiology

Epidemiological studies on cancer provide valuable information that contributes to the overall weight of evidence evaluation on the potential human health hazards from exposure to chlorinated drinking water.

1. Background

The cancer epidemiology literature for cancer and DBPs in drinking water was reviewed and evaluated for the Stage 1 DBPR (USEPA, 1998a). Of the cancer sites, more evidence for a possible association to exposure to chlorinated surface water was available on bladder cancer. For this reason, EPA used the mean risk estimates from the five best studies to quantitate the potential range of risk for bladder cancer from DBPs, expressed as population attributable risk (PAR) (USEPA, 1998g).

While EPA recognized the limitations of the epidemiologic data base for making risk estimates, the Agency believed that it was useful for developing an upper bound estimate of

bladder cancer risk. EPA acknowledged that risks from chlorinated drinking water may be lower than those estimated from the epidemiological literature.

EPA selected studies for inclusion in the quantitative analysis if they contained the pertinent data to perform a PAR calculation and they met a specified set of criteria (USEPA, 1998f). Using these criteria, EPA selected five bladder cancer studies to estimate the PAR range (Cantor, et al., 1985; McGeehin, et al., 1993; King and Marret, 1996; Freedman, et al., 1997; and Cantor, et al., 1998). The PARs were derived from measured risks (OR and Relative Risk) based on the number of years exposed to chlorinated surface water. The calculated PAR range from 2 to 17 percent. This PAR range represents that portion of the bladder cancer population that would be eliminated if the exposure to chlorinated drinking water were absent. The uncertainties associated with these PAR estimates are large due to the common prevalence of both the disease (bladder cancer) and exposure (chlorinated drinking water). Because of the uncertainty in the PAR estimate, EPA recognized that the PAR could also include zero.

From the PARs, EPA estimated that the number of possible bladder cancer cases per year potentially associated with exposures to DBPs in chlorinated drinking water ranged from 1,100 to 9,300 cases. This was based on the estimate of 54,500 new bladder cancer cases per year nationally, as projected by the National Cancer Institute for 1997. Due to the uncertainty in the PAR estimates, EPA recognized that the number of cases could also be zero.

EPA has used this same PAR analysis to estimate the benefits from possible bladder cancer reductions that result from the Stage 2 DBPR (see section VII). For the Stage 2 DBPR analysis, EPA used an updated estimate of 53,200 for the number of new bladder cancer cases per year nationally (projected by the American Cancer Society, 2000).

2. New bladder cancer studies since the Stage 1 DBPR

a. Yang et al. 1998

Yang et al. (1998) conducted an ecologic study of 28 municipalities in Taiwan, where 14 municipalities were classified as exposed (at least 90% of the population was served by chlorinated water), and 14 were classified as unexposed (less than 5% of the population was served by chlorinated water). Average annual age-adjusted sex-specific mortality rates were calculated for specific cancers for the years 1982–1991. The cancers included an "all sites" category plus 11 specific cancer sites: esophagus, stomach, colon, rectum, liver, pancreas, lung, prostate, bladder, kidney, and brain. Each unexposed municipality was matched to an exposed municipality with regard to "urbanization level," which was based on eight ordinal categories that were developed earlier by other investigators. Among females, the standardized rate ratio (SRR) for bladder cancer was 3.92 (CI: 1.08–4.28), and the SRR among males was 1.86 (CI: 1.54–3.50). The Yang et al. study provides some evidence of an association between DBPs and bladder cancer, but several aspects of the study design and results weaken this evidence. The biggest concern about the study's validity is the possibility of residual confounding due to incomplete control of age and urbanization effects.

b. Koivusalo et al. 1998

Koivusalo et al. (1998) conducted a case-control study of bladder cancer and kidney cancer in Finland using incident histologically confirmed cases diagnosed in 1991–1992. Controls were randomly selected from the national population and frequency matched to cases with regard to age (5-year age groups) and sex. The estimated degree of drinking water mutagenicity and cohort exposure to mutagenic DBPs for the years 1950–1987 was based on the

participants' histories of water sources (collected through a self-administered questionnaire) and information from municipal waterworks on past drinking water quality and treatment practices. The overall response rate for the questionnaire was 69%; the percent of people recruited who provided complete exposure information was 57%. After adjustment for age, socioeconomic status, and smoking status, both males and females showed a nonsignificant excess of bladder cancer [odds ratio (OR)=1.2 for both sexes]; male nonsmokers compared to smokers showed a stronger association (OR=2.6; CI: 1.13–5.94) that reached statistical significance. A dose-response analysis based on estimated water mutagenicity tertiles showed no association with bladder cancer. An analysis of exposure duration by 15-year increments showed monotonically increasing ORs among males for both bladder and kidney cancer. When compared to males with <15 years of exposure, the ORs for bladder cancer in males were 1.07 (CI: 0.73–1.55), 1.67 (CI: 1.01–2.78), and 2.32 (CI: 0.99–5.45) for exposure periods of 15–29, 30–44, and $\geq$45 years, respectively. The study provided some evidence for an association between exposure and bladder cancer. However, males showed modest dose-response association with borderline statistical significant, while male nonsmokers showed a fairly strong association.

3. New colorectal cancer studies since the Stage 1 DBPR

a. Yang et al. 1998

The study by Yang et al. (1998), which was previously described, included both colon and rectal cancer as measured endpoints. Among females, the standard rate ratio (SRR) for colon cancer was 0.82 (CI: 0.59–1.14), and the SRR among males was 1.08 (CI: 0.75–1.54); the study provides no evidence of an association between DBPs and colon cancer. In contrast, the sex-specific SRR for rectal cancer was 1.42 ($p<0.05$) for both males and females, indicating a

small association. The main concern about the study's validity is the possibility of residual confounding due to incomplete control of age and urbanization effects.

b. King et al. 2000

King et al. (2000) conducted a case-control study of colon and rectal cancer in which cases were residents of southern Ontario, age 30–74 years at the time of diagnosis (1992–1994), and controls were selected randomly from residential telephone listings. A total of 3,252 colon and rectal cancer cases were identified, but only 44% were included in the analyses due to nonresponse to the questionnaire, lack of physician consent, or lack of sufficiently complete exposure information; 56% of the 2,768 eligible controls were included. Participants provided information during a telephone interview concerning residence history, water source history, and usual amount of water consumption. Estimated levels of THMs in drinking water were based on historical information on residential drinking water characteristics and treatment practices during 1950–1990, and a model that used data from the Ontario Drinking Water Surveillance Program for the years 1986–1992 was used to predict the THM levels in the various water supplies. In addition to the exposure information, the study also collected data on a variety of potential confounders: age, sex, education, body mass index, previous medical conditions, and intake of energy, cholesterol, calcium, alcohol, and coffee.

None of the exposure variables were associated with rectal cancer for either sex, and no exposure variables were associated with colon cancer among females. For males, the risk of colon cancer increased monotonically with duration of exposure to THM levels $\geq$50 Fg/L and to levels $\geq$75 Fg/L; the ORs for exposures $\geq$35 years compared to 0–9 years were 1.68 (CI: 1.02–2.76) for THM $\geq$50 Fg/L and 2.10 (CI: 1.21–3.66) for THM $\geq$75 Fg/L. In the subset of

participants who maintained a constant exposure level for at least 30 years, there was a statistically significant dose-related association for colon cancer and estimated THM level [the highest OR was 1.87 (CI: 1.15–3.05)].

For colon cancer, there was some evidence of an association between both duration of exposure and level of exposure and colon cancer incidence that would support a causal association. The observations were not consistent by gender. The lack of an association with rectal cancer suggests that the study design did not necessarily create a spurious association for colon cancer (i.e., if the colon cancer association was spurious, one might expect also to observe a spurious rectal cancer association). However, the lack of an association among women suggests that the exposure-related risk among women is lower than the risk among men, or that the association among men is spurious. Overall, the study provides evidence of a causal association, but the loss of about half of the eligible participants due to nonresponse and lack of complete exposure information raises concerns about the study's validity.

c. Hildesheim et al. 1998

Hildesheim et al. (1998) conducted a population-based case-control study of colon cancer and rectal cancer in Iowa using the same study procedures and control group as were used in the Cantor et al. (1998) study of bladder cancer (described above in Section 3.1). The study included 685 colon cancer cases, 655 rectal cancer cases, and 2,434 controls. The authors analyzed colon cancer as well as its individual subsites but found no association with duration of exposure to chlorinated surface water or with lifetime THM intake. An analysis of duration of exposure to chlorinated ground water, which adjusted for exposure to chlorinated surface water, found some evidence of an association with colon cancer that did not achieve nominal statistical

significance. For rectal cancer, the analysis of duration of exposure to chlorinated surface water showed a monotonically increasing risk of rectal cancer with OR=2.6 (CI: 1.4–5.0) for the longest (≥60 years) exposure duration compared to the reference category (0 years); the test for trend was statistically significant (p=0.005). A comparable analysis of chlorinated ground water found a weaker association that was not significant; the associations were similar for women and men. Cumulative lifetime THM exposure and average lifetime THM concentration was positively associated with rectal cancer and the test for trend was significant (p=0.01) for the average lifetime THM exposure variable; the associations were again similar for women and men. Dietary fiber intake and physical activity modified the association between chlorinated surface water exposure duration and incidence of rectal cancer: low fiber intake was associated with a larger chlorinated water effect on risk of rectal cancer, as was low physical activity.

The study found essentially no association between the exposure variables and the incidence of colon cancer, although there was a suggestion of an association with duration of exposure to chlorinated ground water. In contrast, there was a statistically significant increased incidence of rectal cancer associated with exposure to chlorinated water as well as to THM. The incidence of rectal cancer tended to increase with increasing exposure for the overall study population. This trend was also apparent for exposure to chlorinated surface water population subsets defined by fiber intake and physical activity. The apparent effect modification from these variables may partially explain the variation in results across studies (i.e., study populations with high levels of fiber intake and frequent physical activity might not show a drinking water effect). The consistency of the dose-response trends, the consistency between sexes, and the apparent control of important potential confounders suggest that the observed

associations between the exposures and rectal cancer may be causal. Although the proportions of eligible cases and controls who were actually included in the analysis with complete information were somewhat low (69.9% for colon cancer cases, 70.6% for rectal cancer cases, and 65.4% for controls), the response rates were comparable to or higher than those for other drinking water studies.

4. New studies on other cancers since the Stage 1 DBPR

In addition to the studies of bladder, colon, and rectal cancer described above, two studies examined kidney cancer [Yang et al. (1998) and Koivusalo et al. (1998)], two studies examined brain cancer [Yang et al. (1998) and Cantor et al. (1999)], one study examined leukemia (Infante-Rivard et al. 2001) and one study examined additional cancers (Yang et al., 1998). These studies are described below.

a. Yang et al. 1998

Yang et al. (1998) conducted an ecologic study of 28 municipalities in Taiwan, where 14 municipalities were classified as exposed (at least 90% of the population was served by chlorinated water), and 14 were classified as unexposed (less than 5% of the population was served by chlorinated water). Average annual age-adjusted sex-specific mortality rates were calculated for specific cancers for the years 1982–1991. The cancers included an "all sites" category plus 11 specific cancer sites: esophagus, stomach, colon, rectum, liver, pancreas, lung, prostate, bladder, kidney, and brain. Each unexposed municipality was matched to an exposed municipality with regard to "urbanization level," which was based on eight ordinal categories that were developed earlier by other investigators. Kidney cancer had a relatively low mortality rate compared to the other cancers, but it had the highest SRR among males (SRR=2.51; CI:

1.27–4.94) and the second highest among females (SRR=2.20; CI: 1.84–5.78). However, no evidence of an association between chlorinated drinking water and brain cancer mortality in either sex was identified. The ORs for females and males were 0.80 and 1.10, respectively. Among females, the only additional cancer that achieved statistical significant association was lung cancer (SRR=1.95; CI=1.45–2.59). Additional significant associations among males included liver cancer (SRR=1.24; CI: 1.01–1.52) and lung cancer (SRR=1.60; CI: 1.39–1.85). Because the Yang et al. study is an ecologic study, conclusions about causality cannot be made.

b. Koivusalo et al. 1998

For the Koivusalo et al. study, which is also described in the previous section, the investigators used the estimated degree of water mutagenicity as the exposure. After adjustment for age, socioeconomic status, and smoking status, the data for males showed a statistically significant excess of kidney cancer (OR=1.47; CI: 1.07–2.02). The data for females exhibited no association between exposure and kidney cancer in any of the analyses. A dose-response analysis based on estimated water mutagenicity tertiles showed monotonically increasing ORs for kidney cancer among males, although the highest OR was only 1.56 (CI: 1.04–2.35). Similarly, an analysis of exposure duration by 15-year increments showed monotonically increasing ORs among males, but they were not significantly different from one; for the highest exposure duration category (≥45 years), the OR was 1.96 (CI: 0.76–2.06) compared to the <15 years category. As noted above in the section on bladder cancer, the low response rate, possible residual confounding, and inconsistent associations by sex weaken the strength of any conclusions regarding possible causality.

c. Cantor et al. 1999

The Cantor et al. (1999) study of brain cancer used the same study procedures and the same control group as used in the Cantor et al. (1998) bladder cancer study (described in Section 3.1) and in the Hildesheim et al. (1999) study of colon and rectal cancer. The study focused on gliomas, and a high proportion of cases (72%) required the use of proxy respondents. The analyses were adjusted for sex, age, farming occupation, and average lifetime population size of the residential community. None of the exposure variables were related to brain cancer among females, but males showed a statistically significant, monotonically increasing risk associated with duration of exposure to chlorinated surface water with OR=2.5 (CI: 1.2–5.0) for exposures $\geq$40 years compared to zero years of exposure. The association with lifetime average THM concentration in drinking water among males was weaker [the highest OR was 1.4 (CI: 0.7–2.9)], although the trend was significant (p=0.04). An analysis that stratified the exposure by median tap water intake level suggested that the increased risk was limited to participants whose tap water intake was above the median level. The analysis used different median intake levels for cases and controls, which may have been inappropriate for dichotomizing the intake levels. Overall, the study provides evidence of an association between chlorination byproducts and gliomas; however, the evidence from these two studies is not strong enough to support or discount a conclusion of a causal association.

d. Infante-Rivard et al. 2001

Infante-Rivard et al. (2001) conducted a population-based case-control study in Quebec Province, Canada, to examine possible associations between childhood acute lymphoblastic leukemia and THMs, five metals (arsenic, cadmium, chromium, lead, and zinc), and exposure to

nitrates during prenatal and postnatal periods. Cases (age 0-9 years at diagnosis) were identified at tertiary care centers, and controls were matched to cases on age (within 2 years), sex, and region within the province; the logistic regression analysis also adjusted for maternal age and maternal level of schooling. Telephone interviews were used to collect information on each child's residential history and the water source used at each residence. The authors used a variety of data sources to estimate past exposures including standardized measurements by the Ministry of Environment for municipal water distribution systems and measurements of THMs, metals, and nitrates in a subset of homes of cases and controls using a standard protocol. However, due to the lack of complete information, only 21% of the person-years of exposure during the prenatal period used values that were not imputed from other years; the percentage for the postnatal period was 26%. Because of missing values, a substantial number of case-control pairs were excluded from analyses of some specific exposures, especially for zinc, where only about half of the case-control pairs were included. There were no associations with leukemia for any of the exposure indices for total THM, specific THMs, nitrates, or any metals other than zinc. Although zinc showed evidence of an association (OR=2.48; CI: 0.99-6.24) for the postnatal period (but not for the prenatal period), the high proportion of case-control pairs excluded due to missing values weakens the evidence for a causal association. Therefore, the study does not provide strong evidence of an association between any of the exposure variables and childhood leukemia.

5. Review of the cancer epidemiology literature (WHO, 2000)

The IPCS report on disinfectants and disinfection byproducts (WHO, 2000) concludes that results of analytical epidemiological cancer studies are insufficient to support a causal

relationship for bladder, colon, rectal, or any other cancer and chlorinated drinking water or THMs. The report notes that there is better evidence for an association between exposure to chlorinated surface water and bladder cancer than for other types of cancer. Because of the large number of people exposed to chlorinated drinking water, the IPCS Task Group concluded that it is important to resolve the issue.

6. Summary of key observations

EPA has evaluated the available cancer epidemiology data concerning drinking water. Based on this evaluation, EPA believes that the cancer epidemiology data provides important information that contributes to the weight of evidence evaluation on the potential health risks from exposure to chlorinated drinking water. At this time, the cancer epidemiology studies are insufficient to establish a causal relationship between exposure to chlorinated drinking water and cancer. However, several studies have suggested a weak association in various subgroups. EPA notes that the recent King study increases the data base of studies that show a possible link between exposure to chlorinated surface water and colon cancer (King, et al., 2000). However, the link to colon cancer is still more tenuous than the link to bladder cancer and EPA does not believe that the data on colon cancer are sufficient for a quantitative analysis. Although the overall cancer epidemiology data do not support a causal interpretation, EPA believes that they do support the decision to pursue additional DBP control measures.

7. Request for comment

EPA requests comment on EPA's conclusions regarding cancer epidemiology and the new studies discussed in today's proposal. EPA also solicits any additional cancer epidemiology data that need to be considered for the final Stage 2 DBPR.

C. Toxicology

The following sections briefly discuss toxicology information received and analyzed since the December 1998 Stage 1 DBPR. Concise summaries of updated and new DBP health assessment documents since the Stage 1 DBPR are included. Additional details are provided in the individual criteria documents. The discussion focuses on TTHM, HAAs, and bromate, because these DBPs are considered in today's proposed rule. Detailed summaries of the health effects data upon which new MCLGs are based are provided in section V.A. of today's proposal. EPA recognizes that disinfected drinking water contains a large number of other DBPs to which people are actually exposed. For this reason, a brief review of information on other DBPs and DBP mixtures is also provided below. EPA has also considered independent reviews of the toxicology literature, including a review by Tyl (2000). This proposal presents the conclusions of these studies and assessments as well as implications for the Stage 2 DBPR.

1. Background

EPA evaluated a large amount of health effects data for the Stage 1 DBPR (USEPA, 1998c). On the basis of the available toxicology data, EPA promulgated a number of DBP MCLGs and maximum residual disinfectant level goals (MRDLGs). EPA established MRDLGs of 4 mg/L for chlorine and chloramine based on toxicity data. EPA published a MRDLG for chlorine dioxide of 0.8 mg/L based on a weight-of-evidence evaluation including information on chlorite and adverse reproductive and developmental effects. The Stage 1 DBPR also established MCLGs of zero for four DBPs based on carcinogenic effects: bromodichloromethane (BDCM), bromoform, dichloroacetic acid (DCAA), and bromate. The Stage 1 DBPR includes MCLGs for dibromochloromethane (DBCM) at 0.06 mg/L, based on a

weight-of-evidence evaluation of cancer and noncancer data, and for TCAA at 0.3 mg/L, based on developmental toxicity and limited evidence of carcinogenicity in animals. The MCLG for chlorite was established as 0.8 mg/L on the basis of a weight-of-evidence evaluation that included developmental and reproductive data.

Today, EPA is proposing new MCLGs for chloroform, MCAA, and TCAA. The derivation of these MCLGs is discussed fully in Section V.A. EPA believes that the remaining MCLGs and MRDLGs established in the Stage 1 DBPR do not need to be revised. The information provided in the following sections adds to the toxicology database but does not change the assessment of the MCLGs.

2. New studies, reviews, and assessments since the Stage 1 DBPR

EPA conducted a literature search of DBPs to identify studies on chronic and subchronic exposures associated with reproductive and developmental, as well as carcingenic effects. The reproductive and developmental studies are summarized in the report *Reproductive and Developmental Toxicity Summary for Selected Disinfection Byproducts* (USEPA, 1999c), while the cancer-related effects are described in the companion paper *Carcinogenic Toxicity Summary for Selected Disinfection Byproducts* (USEPA, 1998l). In addition to these toxicological study summary reports, EPA has developed a number of drinking water criteria documents that evaluate the extant toxicological database for several DBPs and derive quantitative risk estimates when appropriate. Described in the following paragraphs are concise toxicological study summaries for a number of DBPs and whether the conclusions of these studies impact those made in the Stage 1 DBPR.

a. Brominated trihalomethanes

A Draft Preliminary Drinking Water Criteria Document has been developed on brominated trihalomethanes (USEPA, 2001m). This document provides descriptions of studies published since 1994. In consideration of this new information, we conclude that there is no scientific basis for change in the MCLGs for the brominated THMs.

i. Bromodichloromethane

All relevant new studies on bromodichloromethane are on reproductive and developmental effects. The U.S. Army Center for Environmental Health Research (USACEHR) conducted a frog embryo teratogenesis assay - *Xenopus* (FETAX) to evaluate the toxicity of BDCM (USACEHR Test Report, 1999). Frog embryos treated with BDCM with and without metabolic activation experienced spinal abnormalities, with severe malformations evidenced at the higher dose groups. This study demonstrates that BDCM is toxic and teratogenic to frog embryos.

Narotsky et al. (1997) administered BDCM via oral gavage to pregnant rats at dose levels of 0, 25, 50, or 75 mg/kg-day during gestation. Maternal weight gain was significantly decreased at the lowest dose tested, while full-litter resorption (FLR) was observed at 50 mg/kg-day.

The National Toxicology Program (NTP) (1998) conducted a short-term reproductive and developmental toxicity screening study with Sprague-Dawley rats to evaluate the effects of BDCM administered in drinking water for 25 to 30 days. Adverse hepatic effects were identified from this study.

York et al. (2000) conducted a developmental toxicity study with timed pregnant rabbits exposed to BDCM at dose levels of 0, 15, 150, 450, and 900 ppm in drinking water over

gestational days 6 through 29. Maternal toxicity was present at 450 and 900 ppm. The only statistically significant fetal finding was increased incidence of fused sternal centra at 150 and 450 ppm.

Bielmeier et al. (2000) conducted a series of experiments to characterize the effect of BDCM on FLR in two strain of rats. The incidence of FLR in the treated F344 rats was 62%; there were no FLR in all other treatment groups.

Bielmeier et al. (2000) also reported that FLR occurred at specific periods of gestation (6-10 or GD 6-15) for F344 rats. The FLR was accompanied by a marked reduction in serum progesterone concentration without a corresponding drop in luteinizing hormone (LH) levels. The author stated that there may be a disruption of luteal responsiveness to LH as a result of BDCM.

At present, there is information to indicate a possible reproductive hazard (e.g, FLR) from exposure to BDCM via hormonal disruption, but there is insufficient information on the mode of action leading to full litter resorption in this particular strain of rats to fully evaluate the relevance of this data to potential reproductive and/or developmental toxicity in humans.

b. Haloacetic acids

i. Dichloroacetic acid

EPA has completed a 28-day pilot study of medaka fish exposed to DCAA. Treatment-related lethal effects were not observed throughout the 28-day study. The weight of fish in the three highest treatments, 892, 1442 and 2284 mg/L were significantly reduced compared to controls. Liver histopathology was observed in most specimens from the four highest treatments, while mild liver pathology was observed in fish at the 345 mg/L treatment. This

concentration is also lower than the previously reported effect concentration for DCAA-induced liver lesions in medaka (Law et al., 1998). A chronic multi-endpoint medaka bioassay will be completed in February 2002. (Draft-USEPA, 2001g)

EPA's National Health and Environmental Effects Research Laboratory completed a carcinogenicity study in mice exposed to DCAA in drinking water for 90-100 weeks (DeAngelo et al., 1999). The percentage of animals with hepatocellular carcinomas or adenomas was significantly increased at doses of 168 mg/kg/day and above. The number of hepatocellular carcinomas or adenomas per animal (multiplicity) was significantly increased in all treated groups. This study was used to derive the cancer slope factor for DCAA as part of a risk assessment for IRIS (IRIS, 2001). The MCLG for DCAA remains at zero.

c. Bromoacetic acids

EPA has prepared a Preliminary Draft Drinking Water Criteria Document for brominated acetic acids (USEPA, 2000k). The document evaluates monobromoacetic acid (MBAA), dibromoacetic acid (DBAA), and bromochloroacetic acid (BCAA).

The available data on the brominated acids are limited; therefore EPA cannot establish MCLGs for these DBPs. In recognition of the limited database, there is a large body of ongoing research, particularly for BCAA and DBAA. Preliminary results for many studies have been reported in published abstracts and are briefly described below to provide the full spectrum of potential effects induced by brominated acids.

i. Monobromoacetic acid

Toxicity data for MBAA are very limited. Available genotoxicity data for MBAA provide mixed results (Giller et al., 1997; Kohan et al., 1998; NTP, 2000; Stratton et al., 1981). Data are inadequate at this time to conclude on its potential toxicity.

ii. Dibromoacetic acid

In a published abstract, Stauber et al. (1995) reported that DBAA induces liver tumors in B6C3F1 mice. DBAA is mutagenic in *S. typhimurium* assays (NTP, 2000; Giller et al., 1997) and assays for DNA damage repair (Giller et al., 1997). DBAA has also been shown to induce oxidative DNA damage in the livers of mice (Austin et al., 1996; Parrish et al., 1996). On the other hand, no clastogenic effect was reported in a newt micronucleus test (Giller et al., 1997).

The reproductive toxicity database for DBAA was developed to explore the effects of DBAA on the male reproductive system. Early studies showed DBAA to be spermatotoxic (Linder etal., 1994, 1994b, 1995, 1997). Male Dutch Belted rabbits exposured to DBAA in drinking water experienced decreased fertility. Authors conclude that their results "indicate that chronic exposure to DBAA can disrupt male reproductive function and fertility" (Veeramachaneni et al., 2000). However, a 96-hour frog embryo teratogenesis assay on DBAA did not report teratogenic effects with or without metabolic activation (USACEHR, 1999). Taken together, these studies demonstrate that DBAA may be a potent male reproductive system toxicant.

iii. Bromochloroacetic acid

Oral studies of BCAA have identified the liver and the kidney as potential targets of toxicity (Parrish et al., 1996; NTP, 1998). In a published abstract, Stauber et al. (1995) reported

that BCAA induces liver tumors in B6C3F1 mice. BCAA was mutagenic for *S. typhimurium* (NTP, 2000) and induced oxidative DNA damage in the livers of mice given treated drinking water (Parrish et al., 1996).

NTP reported decreased live rat fetuses/litter and decreased total implants/litter in a drinking water study with BCAA (NTP, 1998). Although no effects on male fertility or sperm quality were observed in the NTP study, decreased male fertility was reported in an acute male mice study published as an abstract by Luft et al. (2000). Based on this limited data, BCAA may be a male reproductive toxicant, but inadequate dose response data are available at this time to draw a definitive conclusion.

d. Bromate

EPA has prepared a Toxicological Review of Bromate (USEPA, 2001l) in support of IRIS. Since the Stage 1 DBPR, no new significant studies for bromate have been completed; therefore, the estimate of potential cancer risk for bromate and the MCLG of zero remain unchanged.

e. Other

i. Chlorinated surface water

The U.S. Army Center for Environmental Health Research (USACEHR) conducted a frog embryo teratogenesis assay - *Xenopus* (FETAX) to evaluate the toxicity of TTHMs at a concentration of 3 mg/L in chlorinated surface water and tested three chlorinated surface water samples in the Ames Test. (USACEHR Test Report, 1999).

TTHMs in chlorinated surface water samples were not found to be toxic or teratogenic to frog embryos without metabolic activation. However, with the addition of metabolic activation

in the chlorinated surface water samples, frog embryo toxicity and malformations increased above background levels. None of the three chlorinated surface water samples were mutagenic in two strains (TA 98 and TA 100) of *Salmonella typhimurium* with and without S-9 activation.

ii. MX and chlorohydroxyfuranones

The health effects information in this section is summarized from the EPA document *Quantitative Cancer Assessment for MX and chlorohydroxyfuranones* (USEPA, 2000m). MX (3-chloro-4-(dichloromethyl)-5-hydroxy-2(5H)-furanone) is a byproduct of chlorination typically found at very low concentrations in drinking water.

MX is a potent mutagen in bacterial test systems (Meier et al., 1987; Kronberg and Vartiainen, 1988; Suzuki and Nakanishi, 1990) with consistently positive results reported in multiple strains of *Salmonella typhimurium* and *Escherchia coli*. Overall, the weight of evidence indicates that MX is a direct-acting genotoxicant in mammals.

MX was tumorigenic at multiple sites when doses of 0.4 to 6.6 mg/kg-day were administered to male and female rats via drinking water in a 2-year oral exposure study (Komulainen et al., 1997). The primary sites for tumor formation were thyroid and liver. An oral cancer slope factor of 3.7 $(mg/kg\text{-}day)^{-1}$ was calculated using data for thyroid follicular adenomas in male rats. If an estimated maximum concentration of 67 ng/L is assumed, then the maximum lifetime cancer risk associated with exposure to MX in drinking water is estimated to be 7×10^{-6}.

The Health Assessment document on chlorohydroxyfuranones (CHF) evaluates 28 CHF compounds with limited health effects data. Bacterial assay data suggest mutagenic activity for CHFs is weaker than MX (LaLonde et al., 1991a, 1991b; NTP, 1994; Tikkanen and Kronberg

1990; Kronberg and Franzen 1993). The mutagenic contributions of CHFs to drinking water (with the exception of MX) range from negligible to 1-2% (Smeds et al., 1997).

iii. Chloral Hydrate

EPA has prepared a Toxicological Review of Chloral Hydrate for IRIS (USEPA, 2000n). A new RfD of 0.1 mg/kg-day has been derived based on data reporting central nervous system depression and gastrointestinal irritation in humans (Goodman and Gilman, 1985). The LOAEL is based on a dose of 3.5mg/kg used for sedation. As sedation would not be intended or desirable in the general population, EPA considers this response as an adverse effect and therefore 3.5 mg/kg-day has been used to derive the new reference dose. Data on potential carcinogenic effects, however, are considered inadequate to quantify the cancer risk (i.e., an oral slope factor).

iv. Glyoxal and methylglyoxal

EPA has prepared a Draft Drinking Water Criteria Document for glyoxal and methyglyoxal (USEPA, 2000h), byproducts of ozonation. Genotoxicity studies indicate that both byproducts are mutagenic, but the carcinogenic potential has not been thoroughly studied. Several short-term studies indicate that glyoxal may have cancer-initiating or promoting potential (Takahashi et al., 1989; Martinelli et al., 1988; Furihata et al., 1985a,b). At this time, the carcinogenic potential of glyoxal and methyglyoxal cannot be determined. Small quantities of both chemicals are formed during metabolism in humans and degraded by glyoxylase enzymes.

v. Chlorine dioxide and chlorite

EPA has prepared a Toxicological Review of Chlorine Dioxide and Chlorite (USEPA, 2000c), which is the basis for summary information on IRIS. Since the Stage 1 DBPR, no new relevant studies for chlorine dioxide or chlorite have been completed; therefore, the RfD, MRDLG, and MCLG for these two chemicals remain unchanged.

vi. Chloramine and N-nitrosodimethylamine (NDMA)

Some studies have linked chloramines with N-nitrosodimethylamine (NDMA), a probable human carcinogen as described in EPA's Integrated Risk Information System (IRIS, 1991). Risk assessments have estimated 10^{-6} lifetime risk level of cancer from NDMA exposures at 0.7 ng/L. To date, the research is inconclusive with respect to the extent of formation and the mechanism by which this contaminant is formed.

NDMA is also found in a variety of food products, beverages, drugs, tobacco, industrial water and treated sewage. Although NDMA is mostly a contaminant, Graham et al. (1995) reported its formation in the treatment plant. Given that NDMA was absent in the influent water, but was found post treatment, the authors concluded that it was formed somewhere in the treatment process.

Some coagulant aid polymers used in drinking water treatment have been implicated as precursors of nitrosamines. NDMA formation was reported from the use of some strong-base anion resins. Kimoto et al. (1980) reported NDMA formation when tap water containing residual chlorine was passed through the resin. The quaternary ammonium group present in the resin was believed to be the primary candidate for NDMA precursors (Kimoto et al., 1980).

Najm and Trussell (2000) examined various strong-base anion exchange resins and determined that the composition of the resin affected the levels of NDMA. The dimethyl

quaternary amine resin resulted in the greatest amount of NDMA when compared to the longer chain substituted resins. This indicated that the composition of the resin played an important role in the amount of NDMA formed although the mechanism is not well understood. The authors also compared chlorine and chloramine disinfection using some natural water sources. Although NDMA did not form when chlorine was used, its formation was dependent on the chlorine dose used in chloramination but was independent of the sequence of addition of chloramines. Both natural waters and wastewaters resulted in NDMA formation when disinfected with chloramines (Najm and Trussell, 2000).

The concern over the formation of NDMA in the treatment process is because the compound will persist for a long period of time in the distribution system. An increase in NDMA is also possible when nitrites, formed from the oxidation of ammonia by Nitrosomonas bacteria present in the distribution system, react further with chloramine residual disinfection.

The mechanism of formation of NDMA is still under examination. Its formation has been attributed to the oxidation of secondary amines, such an dimethyl amine, and nitrites by disinfectants. The mechanism of formation is believed to involve the reaction of secondary amines, nitrite and acid, all of which may be present in source waters (Graham et al., 1995). The California Department of Health Services (DHS) initially established an action level of 0.002 µg/L for NDMA in drinking water (1998). In the fall of 1999, and in response to improved analytical methods to measure NDMA in drinking water, a temporary action level of 0.02 µg/L for NDMA was set (DHS, 2000). The Ontario Ministry of the Environment set an Ontario Drinking Water Objective at 9 ng/L (Andrews and Tagushi, 2000).

Some bench-scale studies have shown that pulsed-UV irradiation achieved about 98 percent destruction of NDMA in a California groundwater and that the addition of hydrogen peroxide did not enhance the removal of NDMA but the hydroxyl radicals were effective in degrading the NDMA byproducts. Given that NDMA appears to regenerate after chlorination, the hydroxyl radical was effective in controlling the formation of NDMA when used with pulsed-UV irradiation (Liang et al., 2000).

Research is planned to identify and assess the impacts of seasonal or periodic conversion of chloraminated systems to free chlorine. This study will examine the reasons for chlorine conversion on an intermittent basis. A number of NDMA studies to evaluate occurrence, factors that affect the formation, mechanisms, treatment effectiveness, and improved analytical methods for measuring NDMA are also ongoing. EPA believes that it is important to follow this research; and as more information becomes available, EPA will evaluate the need for possible regulation of NDMA.

3. Reviews of the toxicology literature

a. WHO, 2000

The IPCS report on Disinfectants and Disinfection Byproducts (WHO, 2000) emphasizes that the bulk of toxicology data focuses on carcinogenesis. The Task Group found BDCM to be of particular interest because it produces tumors in both rats and mice at several sites. The Task Group states that although the chlorinated HAAs appear to be without significant genotoxic activity, the brominated HAAs appear to induce oxidative damage to DNA. This activity increases with the degree of bromine substitution.

The IPCS report also notes that significant qualitative and quantitative differences in the toxicological properties of DBPs have been demonstrated, depending on bromine substitution. They noted that the ways in which DBPs induce cancer are also quite different. Brominated DBPs do not necessarily have the same mode of action as chlorinated DBPs.

The report states that in summary, reproductive effects in females have been principally embryolethality and fetal resorptions associated with the haloacetonitriles (HANs) and the dihaloacetates DCAA and DBAA have both been associated with effects on male reproduction.

b. Tyl, 2000

Tyl (2000) surveyed the literature and examined the reproductive and developmental hazard of DBPs (Tyl, 2000). Tyl evaluated the literature as specified by EPA developmental (USEPA, 1991c) and reproductive (USEPA, 1996c) toxicity risk assessment guidelines. These risk assessment guidelines provide a framework for developing judgements of hazard identification (weight of evidence) and determining the adequacy of studies to support dose-response assessments. Studies of DBPs in animal models (and those in progress or in planning stages), are presented in Table III-1, and are categorized as screening studies used for hazard identification or dose response studies used to distinguish between hazard and risk.

Table III-1. Available reproductive and developmental toxicity studies (adapted from Tyl, 2000)

Disinfectant/DBP	Screening [1]	Developmental [2]	Two-generation Reproductive [3]
Chlorine		T	
Chlorine Dioxide	T	T	
Chloramine		T	
Chloroform	T	T	T
Bromoform	T	T	T
Bromodichloromethane	T	in progress	in progress
Dibromochloromethane	T	T	
Monochloroacetic acid	T	T	
Dichloroacetic acid	T	T	
Trichloroacetic acid	T	T	
Monobromoacetic acid	T	T	
Dibromoacetic acid	T	T	in progress
Tribromoacetic acid	T		
Bromochloroacetic acid	T		in planning
Bromodichloroacetic acid	T		
Dibromochloroacetic acid	T		
Chloroacetonitrile	T		
Dichloroacetonitrile	T	T	
Trichloroacetonitrile	T	T	
Bromoacetonitrile	T	T	
Dibromoacetonitrile	T		
Tribromoacetonitrile			
Bromochloroacetonitrile	T	T	
Formaldehyde	T	T	T
Acetaldehyde	T	T	
Propanal	T	T	

Disinfectant/DBP	Screening [1]	Developmental [2]	Two-generation Reproductive [3]
1,1 Dichloropropanone	T		
Hexachloropropanone	T		
Dichloromethane	T		
MX	T	T	
Bromate	T		
Chlorite	T	T	T

T denotes the availability of a study in the following categories.
[1] **Screening studies** are for hazard identification. These types of studies include the following: whole embyo culture, NTP 35-day screening studies, Chernoff-Kavlock and its modified version, short-term male reproductive toxicity screen.
[2] **Developmental study** is the segment II developmental toxicty study.
[3] **Two-generation reproductive study** is the multigeneration reproductive toxicity study.

Tyl concluded that, with the exception of the Chemicals Manufacturers Association (CMA) rat study on chlorite (CMA, 1996), current published studies are not sufficient for quantitative assessment of reproductive or developmental risk but are sufficient for determination of hazard. The data base does indicate that certain DBPs have potential to cause reproductive or developmental effects. (Table III.2).

Table III-2. Potential Hazards of DBPs for reproductive and developmental effects (adapted from Tyl, 2000)

Type of Hazard	DBP
Developmental defects	TCAA, DCAA, MCAA and chlorite
Whole litter resorption	Chloroform, bromoform, BDCM, DBCM, DCAA, TCAA, DCAN, and TCAN
Fetotoxicity (reduced fetal body weights, increased variations)	Chloroform, BCDM, DBCM, DCAA, TCAA, DCAN, TCAN, DBAN, BCAN, MCAN, acetaldehyde, formaldehyde
Male reproductive	DCAA, DBAA, BDCM, formaldehyde

A weight of evidence determination requires an examination of the entire body of literature to provide information on hazard or risk. Tyl concludes that for a number of DBPs, there is the intrinsic capacity to do harm, specifically to the developing conceptus and the male (and possibly the female) reproductive system. However, Tyl does not believe that the extant studies support dose-response evaluations for DBPs.

Tyl concludes that the various *in vitro* and *in vivo* DBP studies satisfy biological plausibility for a number of reasons. One of these reasons include concordance of effects reported in animal toxicity and human epidemiology studies. Effects observed in animal studies which included embryonic heart and neural tube defects, full litter resorption, reduced numbers of implants per litter, and reduced fetal body weight per litter are comparable to the effects observed in some reproductive and developmental epidemiological studies (Tyl, 2000).

4. Summary of Key Observations

The conclusions drawn in the Stage 1 DBPR on the carcinogenic potential of disinfection byproducts remains unchanged by studies completed after the rule was promulgated. The reproductive and developmental toxicological database provides further indications of potential hazards. There are a number of animal toxicology screening studies and alternative biological assays that report adverse reproductive and developmental effects from exposure to certain chlorination byproducts (e.g., BDCM, TCAA, chlorite, DBAA, DCAA, BCAA, DBAA, MCAA and HANs). The adverse health effects evidenced in the toxicology screening studies (e.g., whole litter resorption, reduced fetal body weight) are similar to those reported from the human epidemiology studies (e.g., miscarriage, stillbirth, birth defects, low birth weight) on chlorinated drinking water exposure and reproductive and developmental health outcomes. While these high dose, short-term toxicological screening studies have limitations for use in quantiative risk asssessments, they do contribute valuable information towards an assessment of hazard. EPA believes that the weight of evidence of the reproductive and developmental toxicological and the epidemiological databases suggest that exposure to DBPs may have the potential to induce adverse health effects on male and female reproduction and fetal development at some exposures.

5. EPA Research Program

EPA believes that it is important to pursue the indications of reproductive and developmental hazards and cancer effects from DBPs that have been identified. We have developed both an extensive extramural and intramural toxicology research program that

continues to examine the relationship between exposure to DBPs and potential adverse developmental and reproductive effects, as well as cancer.

EPA has ongoing studies that focus on evaluating the scientific basis for mechanisms of action for TTHMs, DCAA and TCAA. Mutagenicity screening studies are in progress which address the chlorinated drinking water mixtures issue. On reproductive and developmental health effects, EPA is conducting research on the health effects from exposure to DBPs to better enable quantitative risk assessment. In animal models, these studies focus on hazard identification and dose response assessment of haloacetic acids (such as dibromoacetic acid, bromoacetic acid) with respect to effects on both the male and female reproductive systems, and using *in vitro* systems, including proteomics and genomics, to elucidate the scientific basis for common modes of action for reproductive effects of DBPs, and their application to risk assessment. Developmental toxicity studies are focusing on THMs, with particular attention to identify their mechanisms of action on embryo/fetal development. Ongoing effort include identification of critical time windows of exposure with respect to children's health as well as modes or mechanisms of action. Additional details on the types of toxicological studies that are being conducted on DBP cancer, reproductive, developmental and other noncancer health effects may be found on the *M/DBP Research Tracking System* (USEPA, 2000p) (currently under development).

Key features of the extramural effort are collaborations with the Colorado State University and the Research Triangle Institute who are conducting developmental, reproductive and transgenerational studies on priority DBPs (e.g., DBAA and BCAA). Data from these studies will provide dose-response and critical time window vs. cumulative risk information that

will be appropriate for use in formal risk assessment. In addition, a collaborative epidemiology effort is underway to examine the potential for human exposures to DBPs to adverse impact on fertility (time to pregnancy) and semen quality; the latter assessment will incorporate a novel sperm protein developed as a biomarker of DBP effect.

A colloboration with the NTP of the National Institute of Environmental Health Sciences to conduct shorter term and 2 year long term carcinogenicity studies on DBAA, BDCM, DBAN, and BCAA is also underway. This collaborative effort also involves studies at the Department of Defense (DOD), interactions with the American Water Works Association Research Foundation (AWWARF) and future efforts to involve the extramural research community.

6. Request for Comments

EPA requests comment on the weight of evidence evaluation of the potential cancer and reproductive and developmental hazards from DBPs and its potential impacts on the regulatory provisions for the final Stage 2 DBPR. EPA solicits any additional toxicological data on the carcinogenic and potential reproductive and developmental health effects from DBPs that need to be considered for the final Stage 2 DBPR.

IV. Disinfection Byproduct Occurrence

This occurrence section is divided into two main parts and highlights some of the key analyses from the extensive data presented to the Stage 2 M-DBP FACA negotiating committee during the rule development. The first part describes national DBP occurrence data gathered from small, medium and large surface and ground water systems (Sections IV.A. - IV.C.), while the second part describes predicted occurrence data from large surface water systems expected as a result of compliance with the Stage 1 DBPR and the assumptions regarding expected

occurrence for other systems (Section IV.D.). These data were used by EPA to support the development of today's rule.

A. What data sources did EPA use to support today's proposed regulation?

To support the Stage 2 DBPR development, DBP and DBP precursor occurrence data were gathered from a number of sources. The richest data source was the data gathered under the Information Collection Rule (ICR) from systems serving $100,000 persons (USEPA, 1996b).

Occurrence data from medium systems (serving 10,000 to 999,999 persons) and small systems (serving 25 to 9,999 persons) gathered from additional data sources also supported the Stage 2 DBPR: National Rural Water Association Survey (NRWA Survey) (Bissonette et al. 2000, 2001 and USEPA 2001b); ICR Supplemental Survey (USEPA 2001b); State Data; Ground Water Supply Survey (GWSS) and the Water Utility Database (Water:\Stats) (USEPA, 2001b).

This section builds on the occurrence data presented in the Stage 1 DBPR (USEPA, 1998c)) and presents information gathered after the Stage 1 DBPR. The purpose of the occurrence section is to show existing and some anticipated DBP occurrence based on source water and system sizes. The data are presented as national distributions with emphasis on the average and highest levels reported in distribution systems.

A more thorough description and interpretation of the data presented can be found in *Stage 2 Occurrence and Exposure Assessment for Disinfectants and Disinfection Byproducts* (USEPA, 2001b). The Table IV.1. summarizes the data sources that were used for data analyses in support of the Stage 2 DBPR.

Table IV.1. Occurrence Surveys.

Data Source	Data Collection Period	Geographic Representation	Number of Plants (By Population Served)		
			$100,000	**10,000 - 99,999**	**#9,999**
ICR Database[1]	July 97 - Dec 99	All systems serving $100,000 people	501	–	--
ICR Supplemental Surveys	Mar 99 - Mar 00	Random national distribution by SW source type[2]	47	40	40
WATER\STATS	1996	Random National distribution	219	623	30
NRWA Survey	*Warm weather event:* Nov 99 - Mar 00 *Cold weather event:* Aug 00 - Oct 00	Random National distribution	–	–	117
State Data-Surface Water	1998 - 1999	AK, CA, IL, MN, MS, NC, TX, WA[3]	–	–	562
State Data-Ground Water	1998 - 1999	AK, CA, FL, IL, NC, TX, WA[3]	–	–	2336
Ground Water Supply Survey	1983	Random National Distribution (most)	Total: 979		

[1] ICR Auxiliary Database 1 (AUX 1) was used to characterize national occurrence of DBPs , precursors and water quality parameters.
[2] Source type designations include flowing stream and lake/reservoir (Except for 7 large plants pre-selected).
[3] Over 50 percent of each State's systems are represented. In total there are approximately 20 percent of the nations small systems included in these data. EPA believes that the data reasonably represent a full range of source water quality in small systems at the national level.

1. Information Collection Rule

The main data used to support the Stage 2 DBPR are the occurrence data collected under the ICR (USEPA, 1996b), which established monitoring and data reporting requirements for large public water systems. Surface water and ground water systems that serve $100,000 persons were required to conduct DBP and DBP-related monitoring. The 18-month ICR monitoring began in July 1997 and ended in December 1998 and applied to 296 public water systems (501 treatment plants). The ICR data show the national occurrence of: (1) influent water quality parameters; (2) primary and secondary disinfectant use by the large plants; (3) occurrence of DBPs and surrogate DBP precursors in treatment plants, finished waters, and distributions systems; (4) microbial occurrence (in surface water plants only); and (5) treatment plant monthly operation, and initial as well as final treatment plant design. This 18-month data set was collected to provide occurrence of TTHM, HAA5 and bromate, DBPs addressed in today's rule, as well as additional DBPs, relevant water quality parameters, and treatment conditions influencing the formation of DBPs. Table IV.2 summarizes the sampling requirements under the ICR showing the data elements, sampling locations and frequency of sampling. The table does not include additional requirements for purchased finished water, additional water sources, requirements for plants using hypochlorite, nor blended plants. The table does not include microbial monitoring requirements for *Cryptosporidium*, *Giardia*, bacteria and viruses, as these are addressed separately in the proposed LT2ESWTR, which can also be found in today's *Federal Register* (USEPA, 2002).

Table IV.2. Summary of ICR Sampling Requirements (USEPA, 1996)

Data Elements	Sampling Locations	Sampling Frequency
Water quality parameters: (pH, alkalinity, turbidity, temperature, calcium and total hardness)	Plant influent, before and after filtration, before each point of disinfectant addition, finished water, 4 distribution system monitoring locations	Monthly
TOC and UV 254 (Surrogate DBP precursors)	Plant influent, before and after filtration, before each point of disinfectant addition, finished water	Monthly
Bromide and Ammonia	Influent, Influent to ozone contactor	Monthly
Free and total chlorine residuals	At every unit process downstream from the addition of chlorine or chloramine, finished water, 4 distribution system monitoring locations	Monthly
DBPs (TOX, TTHM, HAA6, HAN4, Chloral hydrate, chloropicrin, haloketones and 3 optional HAAs)	Influent (TOX only), after filtration if a disinfectant is added at any point in the plant prior to filtration, finished water, 4 distribution system monitoring locations	Quarterly
Cyanogen chloride (*only plants that used chloramines*)	Finished water, distribution system location representing maximum residence time	Quarterly
Bromate (*only plants using ozone or chlorine dioxide*)	*For plants using ozone*: ozone contactor influent and effluent, finished water *For plants using chlorine dioxide*: before first chlorine dioxide application, finished water	Monthly
Aldehydes (required) Assimilable organic carbon and Biodegradable dissolved organic carbon (optional) (*only plants using ozone or chlorine dioxide*)	*For plants using ozone*: ozone contactor influent and effluent, finished water *For plants using chlorine dioxide*: before first chlorine dioxide application, before first point of chlorine or chloramine application after chlorine dioxide addition, finished water	Quarterly

2. ICR Supplemental Survey

The ICR Supplemental Survey (ICRSS), conducted by EPA, was designed to supplement ICR information on microbial occurrence and source water quality. The Supplemental Survey was conducted at 120 randomly selected plants (40 treatment plants in each category of small,

medium, and large surface water plants). Seven very large systems (> 1 million people served) were also included in the survey effort. Monitoring (twice a month at each plant) was conducted for 12 consecutive months beginning in March, 1999. All survey participants, except for small systems, collected protozoan data. Large systems collected limited influent water quality data (TOC), while medium and small systems monitored additional water quality parameters (temperature, pH and alkalinity) and surrogates for DBP precursors (TOC , UV-254 and bromide). EPA used these data to compare relative treatability among different size categories for achieving compliance with the Stage 2 DBPR regulatory options. A discussion of the protozoa data is included in the proposed LT2ESWTR, which can also be found in today's Federal Register (USEPA, 2002).

3. National Rural Water Association survey

In 1999, The National Rural Water Association (NRWA) and EPA began a data collection effort to gain a better understanding of water quality, byproduct occurrence, treatment plant configurations, and disinfection practices in small surface water systems. The NRWA Survey, supported by EPA and NRWA State chapters, included two sampling periods that represent cold and warm weather events: November 1999 - March 2000 and August - October 2000. A random set of systems (117) serving fewer than 10,000 people were selected and relevant DBPs and precursors were measured. Precursor data (e.g., TOC and bromide) were gathered for plant source waters and TTHM and HAA samples were collected at three locations: plant finished water, estimated distribution system average, and estimated maximum residence times. The NRWA survey data were used to understand both the impact of the Stage 1 and 2

DBP rules on small systems and how these systems compare to larger surface water system treatment and occurrence (Bissonette et al., 2000 and USEPA, 2001b).

4. State data

Small system data collected by a number of States also support the characterization of DBP occurrence among these systems (USEPA 2001b). Although small systems were not required by EPA to comply with the TTHM rule, a number of States made efforts to conduct small system TTHM occurrence monitoring or required compliance with the TTHM MCL. These States provided the data to EPA. Data from eight States (Alaska, California, Illinois, Minnesota, Missouri, North Carolina, Texas and Washington) had sufficient information on TTHM in small surface water systems and were included in further analyses. Similarly, TTHM data for small ground water systems from seven States (Alaska, California, Florida, Illinois, North Carolina, Texas and Washington) were further analyzed. These State datasets included samples that represented at least 50 percent of each State's small water systems and in total accounted for about one-fifth the number of all small surface water systems in the U.S. EPA believes that these data represent the geographical distribution of average annual TTHM occurrence among small systems in the U.S.

5. Ground Water Supply Survey

The Ground Water Supply Survey (GWSS), conducted by EPA in 1981 and 1982, remains one of the most extensive and useful surveys of US ground waters. The GWSS was a sampling and analysis study of the levels of volatile organic compounds (VOCs) in ground water. The data were collected from 979 sites: half were selected randomly to provide a broad national perspective on the incidence of VOC contamination, and the other half selected non-

randomly to allow States to identify sites that were presumed to have high levels of VOCs for further investigation. Included in the sampling were levels of finished water TOC and TTHM. Although TTHM data were available in the survey, EPA did not use the TTHM data because samples were collected at the point of entry to the distribution system rather than from the distribution system and more recent TTHM data were available from the States. EPA used the TOC data from the GWSS to indicate the extent to which TOC occurs on a national basis and for helping to predict the numbers of ground water systems which might be affected under the proposed Stage 2 DBPR. Even though the TOC data from the GWSS were collected about 20 years ago, EPA believes these data are still valuable.

6. The Water Utility Database

The Water Utility Database (Water:\Stats) is a database that contains general information about water utility operations collected by the American Water Works Association (AWWA) in a 1996 survey of 900 utilities. The Water:\Stats data discussed today includes influent TOC and distribution system TTHM levels reported for large and medium systems. These data support the characterization of medium surface and ground water systems for the Stage 2 DBPR (USEPA, 2001d). The data were used to evaluate the similarity of medium and large systems and to determine whether predictions of DBP occurrence and compliance choices based on influent ICR water quality and treatment could be extrapolated to medium systems. Table IV.3. presents a summary of the non-ICR databases used to support the Stage 2 DBPR.

Table IV.3. Summary of Non-ICR Occurrence Survey Data.

Data Source	Raw Water Quality Data	Treatment Data	Finished Water Quality Data
ICR Supplemental Survey	- Two samples per month for 12 months - *Cryptosporidium*, *Giardia*, total coliform, and E. coli (no protozoa sampling for small systems). - Large Systems - 2nd sampling of month included TOC - Small & Medium Systems- 2nd sampling of month included: TOC, UV 254, bromide, turbidity, pH, & temperature	–	--
The Water Utility Database	- Annual average, minimum, and maximum levels of WQPs (Including TOC & total dissolved solids (TDS)) - Population served and flows - Source water types	- Treatment unit processes - Chemical and disinfectant use	Annual average, minimum, and maximum levels of: - WQPs - chlorine residuals - TTHM in both finished water and distribution systems - HAAs in distribution systems
NRWA Survey	- Annual average and minimum sample time temperatures - Turbidity , pH, population served, flow, and source water type - Bromide, TOC, UV 254, alkalinity, calcium and total hardness	- Treatment unit processes - Chemical and disinfectant use	- Average and maximum residence time estimate - Total and individual THMs, individual HAAs and HAA5, HAA6, HAA9 at finished water, average and maximum residence time sample sites - Finished water turbidity, TOC, UV 254, and Bromide - Temperature, pH, free and total chlorine residual levels at finished water, average and maximum sites
State Data - Surface Water	–	--	Distribution system TTHM occurrence data
State Data - Ground Water	–	--	Distribution system TTHM occurrence data
Ground Water Supply Survey	–	--	TOC and TTHM (one sample for each parameter at the entry point to distribution system.)

B. Summary of occurrence of DBPs addressed in today's rule

This subsection focuses on the occurrence of TTHM, HAA5, and bromate, the DBPs addressed in today's rule. To support the information on DBP occurrence, the national plant mean distributions of TOC, UV 254 and bromide (surrogates for DBP precursors) are reported, where available. Information concerning other DBPs and water quality parameter data collected in the ICR and other data sources that are not addressed herein can be obtained from *Stage 2 Occurrence and Exposure Assessment for Disinfectants and Disinfection Byproducts* (USEPA 2001b).

1. Large surface water and ground water systems - ICR data

DBP formation is dependent on many factors including precursor levels (indicated by concentrations of TOC, bromide and UV 254 absorbance), disinfectant type and dose, contact time, temperature, pH and distribution system conditions. These and other parameters were monitored in the ICR based on the rule requirements as shown in Table IV.2. TOC and UV 254 are surrogates or "indicators" of the organic material that reacts with disinfectants to form DBPs. For simplicity, these are referred to as "precursors" in this discussion.

Plant influent water quality data from the ICR show the variability in the precursor levels and selected disinfectant types used by surface and ground water systems that serve $100,000 persons. Plants served by surface water sources make up about 72 percent of the 18-months of reported data (or plants/month records), with 57 percent using chlorine disinfection in their water treatment plants. About 26 percent of these surface waters plants use chlorine combined with chloramine, or chloramine alone, 5 percent use ozone and 6 percent use chlorine dioxide (Note that 6 percent of the plants did not report plant disinfectant type). For the ground water plants

(26 percent of ICR plant/month records), about 57 percent use no disinfectant in the treatment plant, 30 percent use chlorine, only 12 percent use chlorine combined with chloramine or chloramine, and less than 1 percent use ozone. The sum totals of source water type or disinfectant type may not add up to 100, given that some data entries were missing because these plants did not report these data.

In the distribution system, residual disinfectant type for surface waters is comprised of 68 percent chlorine and 32 percent chloramine, while 87 percent of ground waters use chlorine and 11 percent use chloramine (Note that two percent of the plants did not report the type of residual disinfectant used).

The data presented in this section are for plant means calculated for the last twelve months of the ICR monitoring (January 1998 to December 1998). Only plants that have at least nine months of reported data (or at least three quarters for parameters that were monitored quarterly) are included in the calculation of the plant means. Treatment plants monitored water quality parameters, DBP precursors and some DBPs monthly, and the majority of the DBPs quarterly. Sampling locations and monitoring frequencies are shown in Table IV.2.

The ICR data shown in Table IV.4 is from the Auxiliary 1 database, Version 5 (USEPA, 2000d), and is aggregated by source water category. This auxiliary database was created to facilitate the ICR data analysis process that supported the development of the rule. The database contains ICR data reported by the plants and validated according to the requirements of the ICR (USEPA, 1996) to ensure that the highest quality data was used to support the rule. A number of other databases (Auxiliary 2 - 8) were also developed to facilitate the data analyses. These and other tools were used by the technical workgroup to understand the mass of data that was

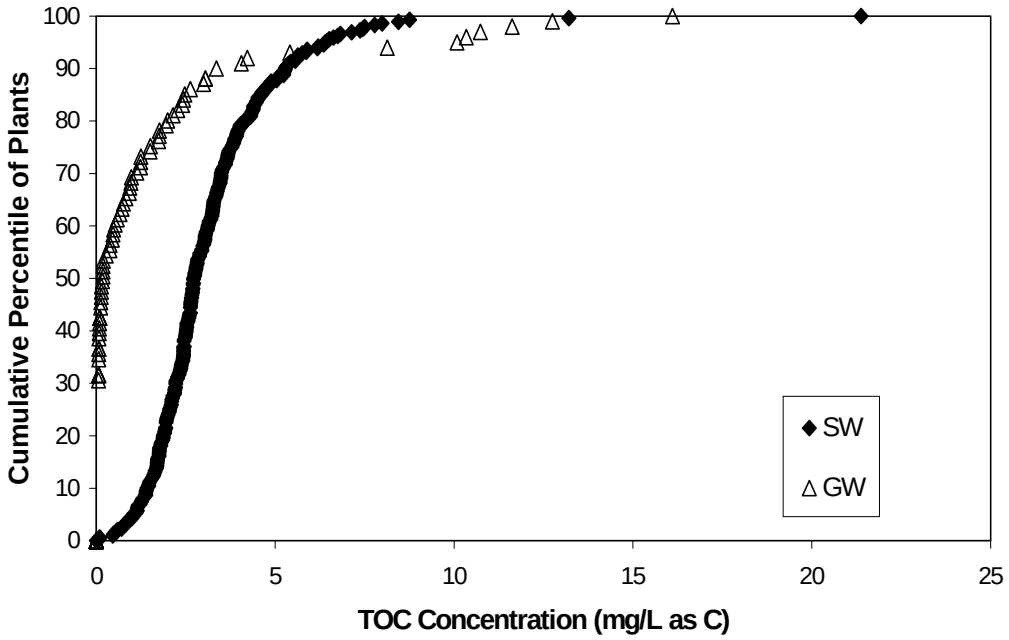
generated under the ICR (and gathered from non-ICR sources) and to present the results to the negotiating committee. A summary of the most pertinent ICR results are presented in this subsection.

The summary statistics for the cumulative probability distribution of the 12 month plant mean influent precursor levels (mean, median and 90th percentiles) are presented in Table IV.4. The plant mean ranges are also presented. The plant mean cumulative probability distributions for surface and ground water TOC and bromide levels are shown in Figures IV.1 and IV.2, respectively.

Table IV.4. Summary of Plant mean ICR Precursor Data, Influent Water.

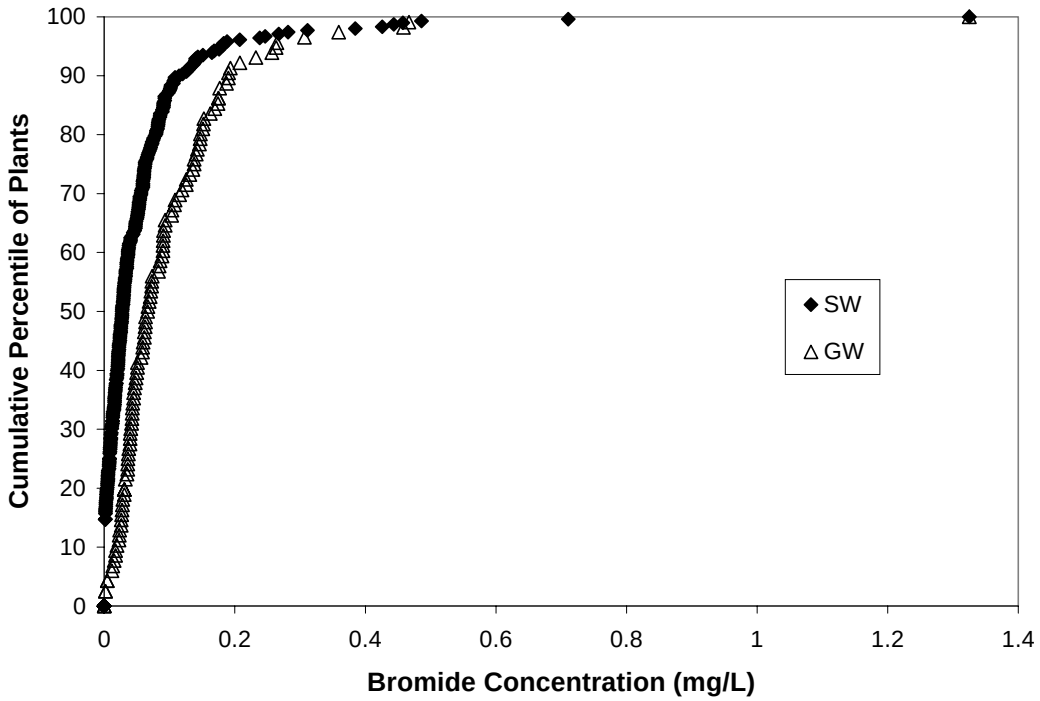
Source	Number of Plants	Mean of Plant Means	Median	90th Percentile	Range
Bromide (mg/L)					
Surface	314	0.056	0.027	0.125	0 - 1.325
Ground	117	0.103	0.065	0.190	0 - 1.325
Total Organic Carbon (mg/L as C)					
Surface	298	3.16	2.74	5.26	0 - 21.4
Ground	102	1.47	0.16	3.36	0 - 16.1
UV - 254 Absorbance (cm^{-1})					
Surface	299	0.100	0.082	0.177	0 - 0.880
Ground	103	0.063	0.010	0.265	0 - 0.606

Figure IV.1. Distribution of Plant Mean TOC Concentration in ICR Surface and Ground Waters.



Influent precursor concentrations (TOC and UV 254) are higher in surface waters than in ground waters for at least 90 percent of the plants, whereas bromide concentrations are higher in ground waters. In general, TOC and UV 254 change significantly with treatment and affect the formation of DBPs in the distribution system. Processes such as coagulation and clarification remove both TOC and UV 254, DBP precursors, and oxidation decreases UV 254 absorbance. The bromide concentration was measured in the influent to the ICR plants but was not measured throughout treatment. The bromide concentration is considered to be conservative through physical treatment processes but reacts with oxidants like chlorine and ozone.

Figure IV.2. Distribution of Plant Mean Bromide Concentration in ICR Surface and Ground Waters.



The influent precursor levels presented in Table IV.4. and Figures IV.1 and IV.2 show the wide range of precursor concentrations observed nationally in ICR plants. The wide range in these precursor levels and ICR disinfectant types influence the TTHM and HAA5 plant mean concentrations observed in large surface and ground water ICR systems that are presented in Table IV.5.

TTHM and HAA5 data were collected quarterly in four locations in distribution systems associated with each ICR treatment plant. Two samples were collected at sites representing average contact times (AVG1 and AVG2) , one sample at a site representing what the utility believed to represent its maximum residence time (MAX), and one sample, reported as a distribution system equivalent (DSE) (the DSE sample was generally representative of average contact times).

The data shown in Table IV.5. is from Auxiliary 1, Version 5 (USEPA, 2000d), and is aggregated by source water category. The summary statistics for the plant mean cumulative probability distribution of the last four quarters of distribution system data (mean, median and 90^{th} percentiles) are presented in the table. The column labeled "Parameter" in Table IV.5. shows the calculated average value (DS Average) of the four distribution system sampling locations for the four quarters, and a (Single Highest) value, which is selected from the reported data. The distribution system average (DS Average) is comparable to a running annual average and the distribution system single highest value (per plant) is the single highest concentration reported for four locations over the four quarters. The single highest value for TTHM and for HAA5 may not be reported from the same location nor reported for the same quarter. The

cumulative percentile distributions for surface and ground water TTHM and HAA5 RAA data are shown in Figures IV.3 and IV.4, respectively.

Table IV.5. Summary of ICR Distribution System TTHM and HAA5 Data.

Source	Number of Plants	Parameter	Mean	Median	90th Percentile	Range
TTHMs (µg/L)						
Surface	268	DS Average	43.2	41.0	70.4	0 - 134
Ground	95	DS Average	16.7	7.6	49.0	0 - 123
Surface	292	Single Highest	70.6	65.0	119	0 - 322
Ground	89	Single Highest	35.1	20.4	75.2	0 - 300
HAA5 (µg/L)						
Surface	257	DS Average	29.4	24.9	52.0	0 - 116
Ground	98	DS Average	8.9	2.6	27.0	0 - 70.8
Surface	287	Single Highest	49.5	41.0	93.0	0 - 280
Ground	95	Single Highest	16.6	6.4	45.4	0 - 124

Figure IV.3. Distribution of TTHM RAA Data in ICR Surface and Ground Waters.

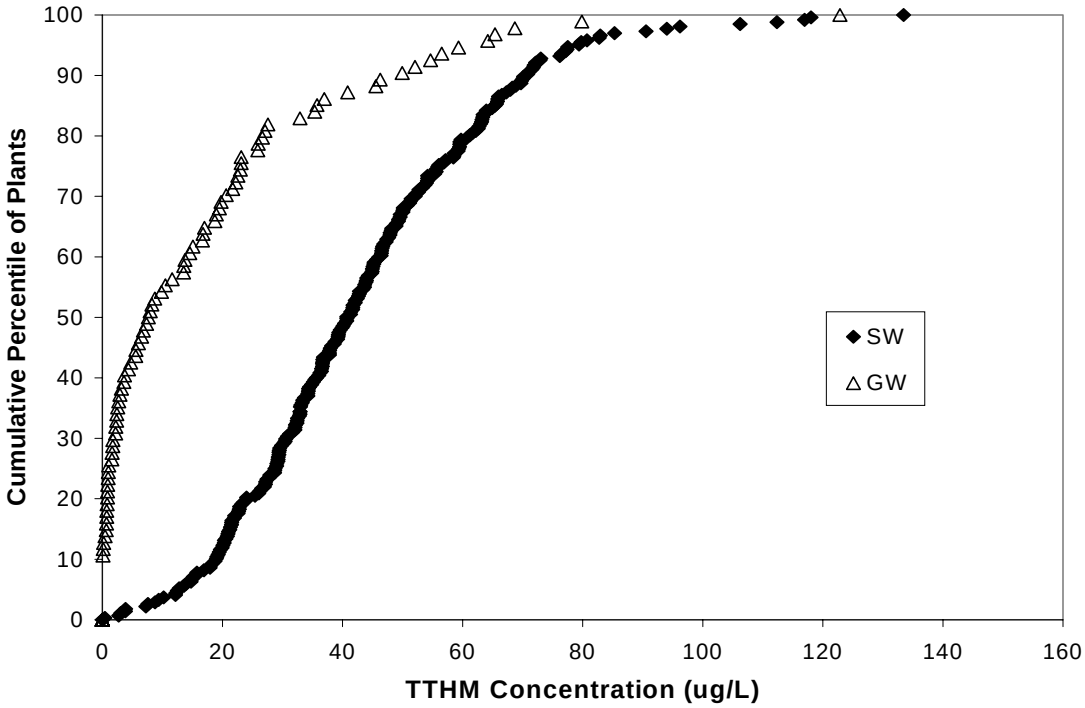
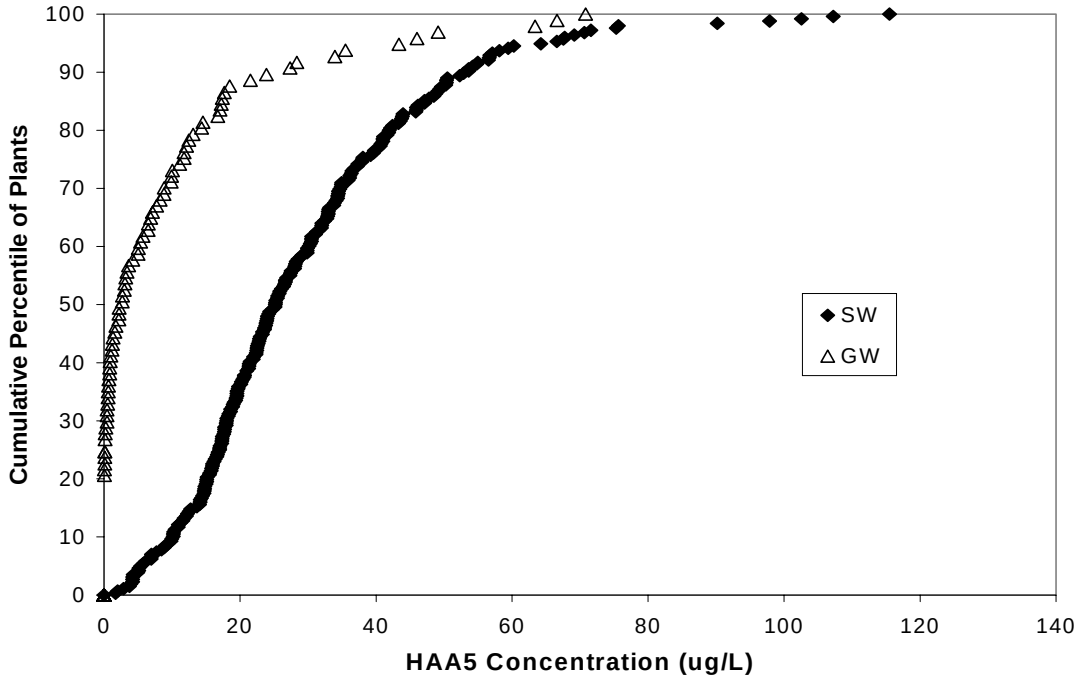


Figure IV.4. Distribution of HAA5 RAA Data in ICR Surface and Ground Waters.



In general, TTHM and HAA5 levels in distribution systems of surface water plants are much higher than those for ground water plants. While the 90th percentile RAA levels are less than the MCLs for TTHM and HAA5, the upper bounds of the ranges indicate that some plants have mean levels that exceed the MCLs (it is important to note that the MCLs for TTHMs and HAA5 were not yet in effect during the ICR sampling and that the actual monitoring locations for determining compliance with the MCLs may be different than the monitoring locations used during the ICR). The single highest TTHM and HAA5 values in Table IV.5 indicate some locations in the distribution system can have substantially higher TTHM or HAA5 levels than what is represented by the mean concentration (i.e., when the data are averaged spatially and temporally in the distribution system as in a RAA).

This is further illustrated by the cumulative percentile distribution plots of six quarters of ICR data for the four distribution system locations, shown in Figures IV.5 and IV.6, for TTHM and HAA5, respectively. These data, for the ICR surface water plants, are actual observations and do not represent the plant means. Figures IV.5 and IV.6 indicate the extent to which high TTHM and HAA5 levels occur at each of the designated ICR sampling locations. Levels up to 300 µg/L are reported.

At the time of the ICR, systems were not required to operate on the basis of compliance with the Stage 1 DBPR, although some systems were proactive and had made treatment changes to improve precursor removal through enhanced coagulation. Compliance with the Stage 1 MCLs results in a general decrease in exposure to DBPs for all systems, but will not necessarily result in all consumers in the distribution system being protected below the MCL levels. This is

because the Stage 1 DBPR compliance is based on an RAA and DBP levels are averaged spatially and temporally in the distribution system.

Figure IV.5. Cumulative Probability Distribution of TTHM Levels in Four Distribution System Locations.

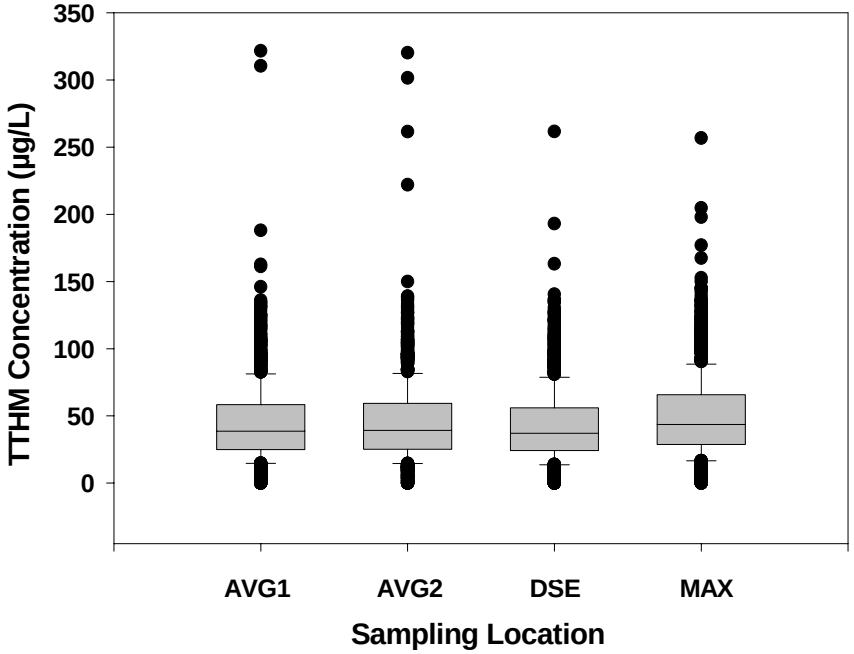
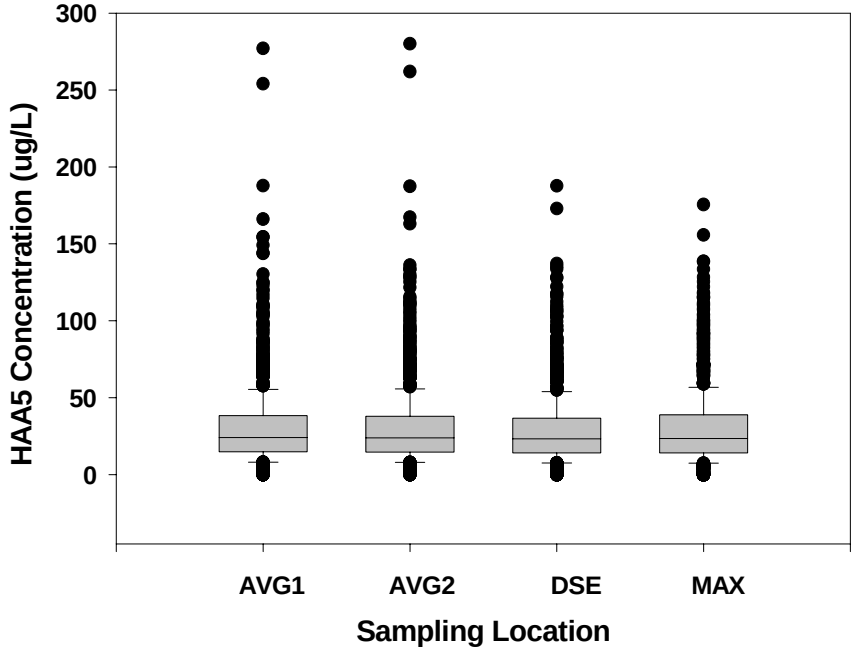


Figure IV.6. Cumulative Probability Distribution of HAA5 Levels in Four Distribution System Locations.



Figures IV.7 and IV.8 depict the RAA TTHM and HAA5 data for surface and ground water plants, respectively. The HAA5 data are plotted versus the TTHM data, as paired samples, and the MCL limits for both DBP classes are shown on the figures. The percent of plants in each quadrant are shown in the figures. In Figure IV.7, the lower left quadrant represent treatment plants that have TTHM and HAA5 RAA values lower than the MCLs (91.4 percent). The upper left quadrant represents samples where the TTHM RAA concentrations are less than the MCL, but HAA5 RAA concentrations exceed the MCL of 0.060 mg/L (4.8 percent). Similarly, the right lower quadrant shows TTHM RAA values exceed the MCL, but the HAA5 RAA values are lower than the MCL (2.4 percent). The upper right quadrant represents plants that neither meet the TTHM or HAA5 MCLs (1.4 percent). Collectively, 8.6% of the plants were not meeting either the THHM or HAA5 MCLs during the time of ICR monitoring. Ground water plant RAAs shown in Figure IV.8 indicate that most of the plants are currently meeting the Stage 1 DBPR (97.4 percent).

Figure IV.7. Comparison of ICR Distribution System TTHM and HAA5 RAA Results for Surface Waters.

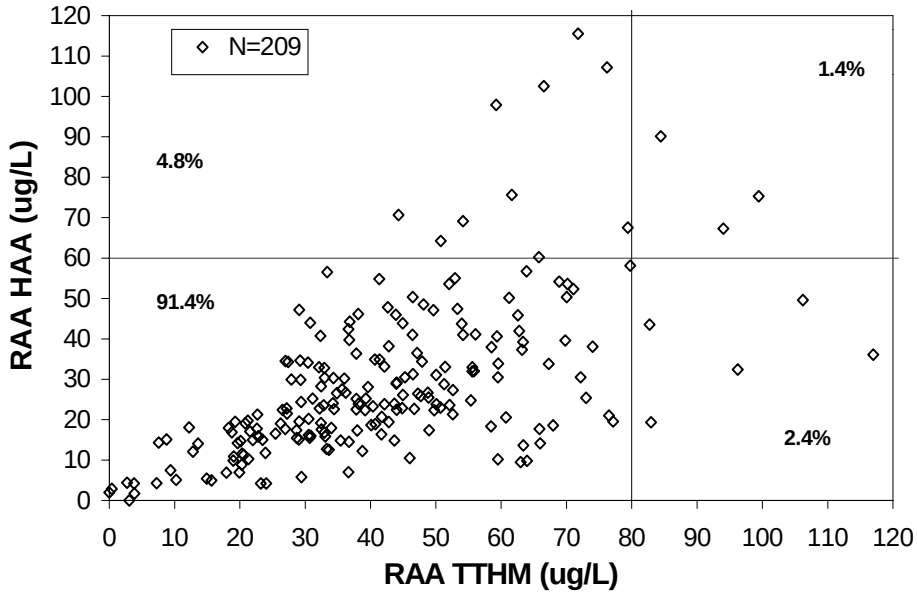
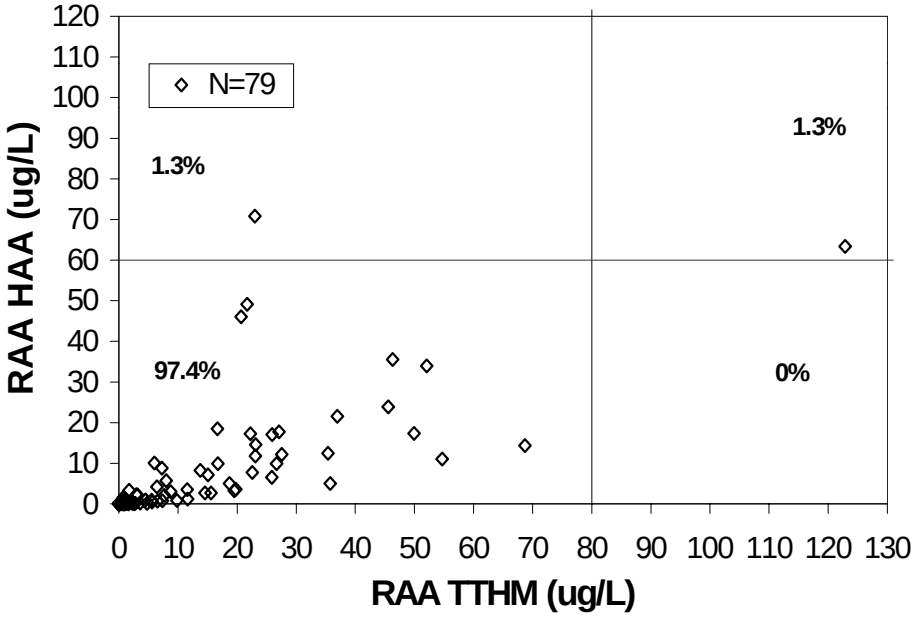


Figure IV.8. Comparison of ICR Distribution System TTHM and HAA5 RAA Results for Ground Waters.



2. Medium and small surface and ground water systems

A summary of the non-ICR data used to support the development of the rule is presented in Table IV.6. The table shows the summary statistics for the 12 months plant mean DBP precursor data from small and medium size systems from various sources. System size and source water based details are presented in the three sections that follow: a. Medium surface and ground water systems; b. Small surface water systems; and c. Small ground water systems.

Table IV.6. Summary of Plant Mean Non-ICR Precursor Data (TOC, Bromide & UV254).

System Source/Size Category	Number of Plants	Mean	Median	90th Percentile	Range
Source Water TOC Data (mg/L as C)					
NRWA Survey Data[1]					
Small Surface Water Plants	102	3.1	2.6	5.4	0.33* - 11.4
Supplemental Survey					
Large Surface Water Plants	47	3.2	3.0	4.9	0.7 - 31
Medium Surface Water Plants	40	3.6	3.6	5.5	0 - 22
Small Surface Water Plants	391	2.4	1.8	6.1	0 - 17
WATER:\STATS					
Large Surface Water Plants	148	3.6	3.2	5.9	0 - 26
Medium Surface Water Plants	99	5.6	3.2	6.4	0 - 200
Large Ground Water Plants	38	2.0	1.0	3.5	0 - 14
Medium Ground Water Plants	51	2.3	0.79	7.0	0 - 25
Source Water Bromide Data (mg/L)					
NRWA Survey Data[1]					
Small Surface Water Plants	102	0.085	0.023	0.112	0 - 2.5
Supplemental Survey					
Medium Surface Water Plants	40	0.050	< 0.020	0.090	0 - 0.530
Small Surface Water Plants	40	0.020	< 0.020	0.040	0 - 0.290
Source Water UV 254 Data (cm^{-1})					
NRWA Survey Data[1]					
Small Surface Water Plants	102	0.084	0.076	0.139	0.012 - 0.592
Supplemental Survey					
Medium Surface Water Plants	40	0.093	0.083	0.171	0.029 - 0.208
Small Surface Water Plants	40	0.079	0.055	0.115	0.079 - 0.424

[1] Summary statistics from the distribution of all survey results (cold and warm weather samples).
* For these data, the minimum reporting level = 0.2 mg/L

a. Medium surface and ground water systems

The Water Utility Database and the ICR Supplemental Surveys (ICRSS) provide information for DBP precursors (Table IV.6) for medium surface water systems. As shown in Table IV.6, the median and 90th percentile of plant mean TOC data in the source waters of medium surface water systems are very similar to that of large surface water systems in both the Water:\Stats and ICRSS data. In addition, the distribution of plant mean UV 254 absorbance reported for medium systems in the ICRSS are generally similar to those reported for large surface water plants in the ICR (see Table IV.4). The median and 90th percentiles are similar in the Water:\Stats data for these two system categories. Other areas of similarity between these system size categories include:

- use of water source type,
- distribution of treatment technologies,
- major categories of treatment,
- use of key unit processes, and
- the use of specific disinfection methods among conventional plants (USEPA, 2001).

The Water Utility Database also provides precursor and TTHM occurrence data for medium ground water systems (Tables IV.6 and IV.7). As with the medium surface water systems, the data reflect similarities in treatment used, source water TOC levels and TTHM occurrence between large and medium systems.

While the data available for medium systems are limited when compared to the ICR dataset, EPA believes that they provide a comparable basis for concluding that source water

quality parameters, current treatment configurations, and DBP levels in treated waters for medium systems are similar to those observed for large systems.

Table IV.7. Summary of Plant Mean Non-ICR DBP Data.

Source	Data Type	No. of Samples	Mean	Median	90th percentile	Range
TTHM (Fg/L)						
NRWA Survey Data[1]						
Small Surface Water Plants	Finished	103	64.4	7.5	136	0 - 326
	DS Average	103	82.6	59.6	185	0 - 329
	DS Maximum	103	92.6	68.8	188	0 - 326
8-State Data Set[2]						
Small Surface Water Plants	Mixed	562	99	66	215	0 - 687
WATER:\STATS						
Large Surface Water Plants	Finished	215	41	40	69	0 -100
	DS	135	44	45	70	0 - 91
Medium Surface Water Plants	Finished	211	40	41	70	0 - 91
	DS	195	42	44	73	0 - 96
Large Ground Water Plants	Finished	70	16	5.5	45	0 - 91
	DS	48	23	12	56	0 - 91
Medium Ground Water Plants	Finished	213	15	7.0	44	0 - 103
	DS	232	19	10	51	0 - 121
HAA5 (Fg/L)						
NRWA Survey Data[1]						
Small Surface Water Plants	Finished	103	42.6	32.2	81.5	0 - 327
	DS Average	103	46.9	36.4	89.8	0 - 328
	DS Maximum	103	44.1	37.2	90.4	0 - 182

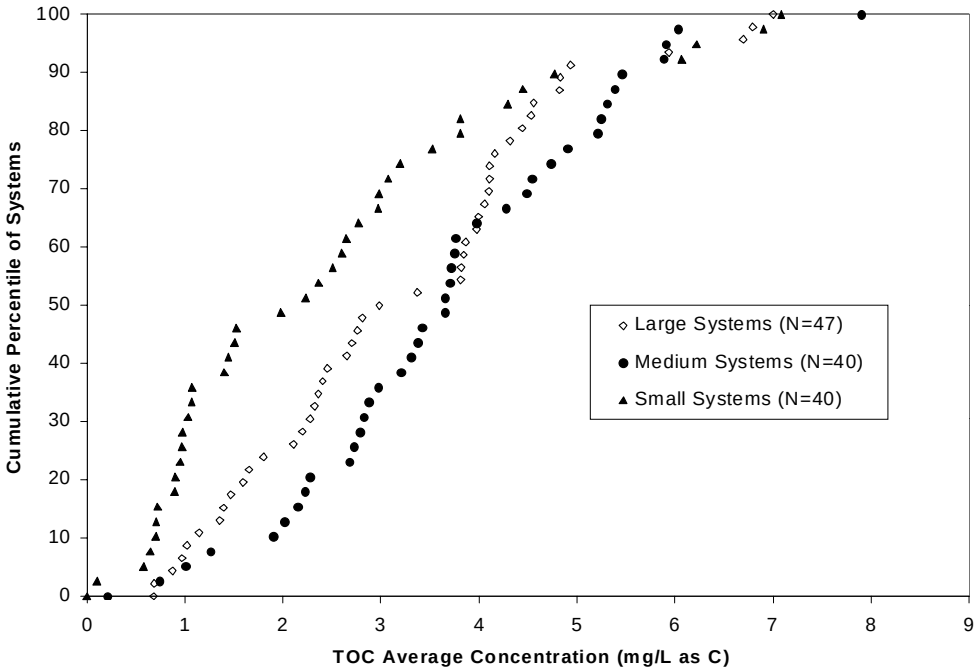
[1] Summary statistics from the distribution of all survey results (cold and warm weather samples).
[2] Most plants have only one measurement.

b. Small surface water systems

There are several key sources that provide precursor and DBP data for small surface water systems. These include the ICR Supplemental Survey, the NRWA Survey, and some State data.

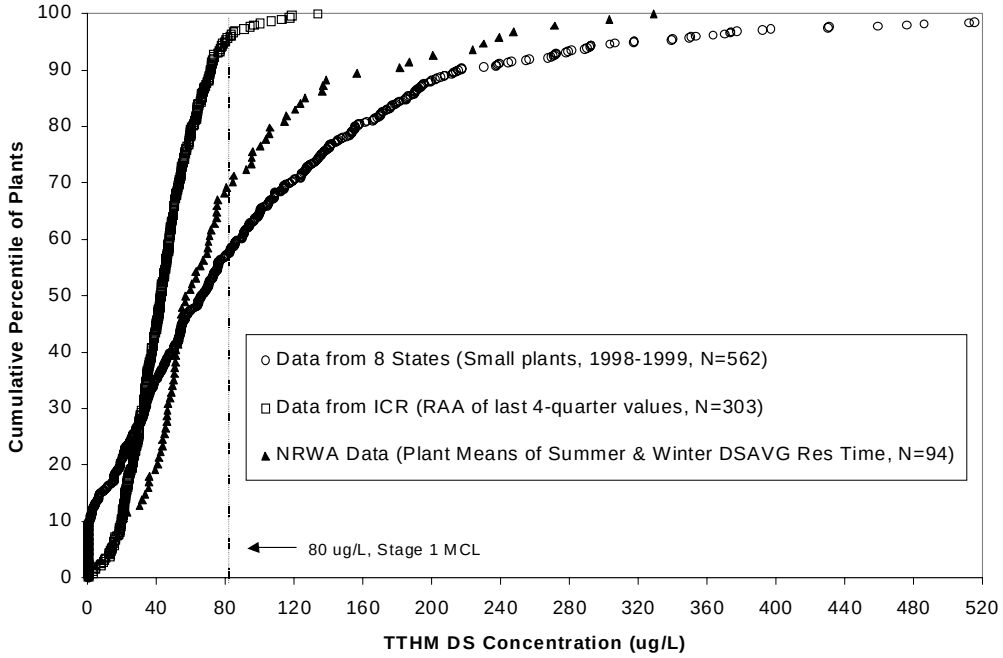
The ICRSS data in Table IV.6. indicate that TOC levels for small surface water plants differ somewhat from that for the medium and large plants. Figure IV.9 shows that small plants generally have lower TOC levels than do the medium and large plants, suggesting that a smaller percentage of systems in the small size category may have to use advanced disinfectants (e.g., chlorine dioxide or ozone) or advanced treatment (e.g., GAC or membranes) to comply with the DBP MCL requirements from the Stage 1 DBPR or the proposed Stage 2 DBPR. However, it is important to note that the small, medium, and large system data are similar at the upper end of the TOC distributions. Table IV.6. also shows that small system Supplemental Survey bromide and UV-254 absorbance levels are lower than those for large systems, also suggesting less need for advanced processes.

Figure IV.9. ICR Supplemental Survey Influent TOC levels.



Despite the above precursor data, the current data available from the NRWA Survey and States on DBP levels in small surface water systems indicate higher byproduct levels than in large systems (Table IV.6 and Figure IV.10). This is understandable, given that small systems, unlike large systems, have not been subject to the requirements of the 1979 TTHM standard. Figure IV.10 shows that, in the ICR data, about 5 percent of large plants have average distribution system TTHM levels higher than 0.080 mg/L. These percentages are higher for small systems: the State surface water data indicate that about 42 percent of plants exceed 0.080 mg/L; and the NRWA survey data show 30 percent of plants exceeding this level.

Figure IV.10. Average Distribution System TTHM Occurrence in Surface Water Plants.



c. Small ground water systems

Although data are not available on influent TOC levels for small disinfecting ground water systems, there are some data available on effluent (finished water) TOC in small, medium and large disinfecting ground water systems. These data provide insight into how small system DBP precursor levels compare with those at larger systems.

Figure IV.11 provides the effluent TOC data obtained in the 1982 GWSS (USEPA 2001b). Though this information is somewhat dated, EPA assumes the following with respect to these data:

- the fraction of TOC removed in these systems is probably not substantial due to the general lack of treatment to remove precursors; thus these effluent TOC levels are indicators of influent TOC [Figure IV.12 provides evidence of this in the Water:\Stats data, particularly when TOC is < 8 mg C/L] ;
- the levels of TOC in influent ground waters probably have not changed much since these data were collected (support for this is provided by comparing the effluent data for the large systems in the GWSS data to the observed influent TOC levels for large systems in the ICR); and
- the comparison across system sizes indicates that, on a national scale, TOC levels in small disinfecting ground water systems are similar to those of medium and large systems.

Figure IV.11. Comparison of Effluent TOC for Chlorinating Ground Water Systems.

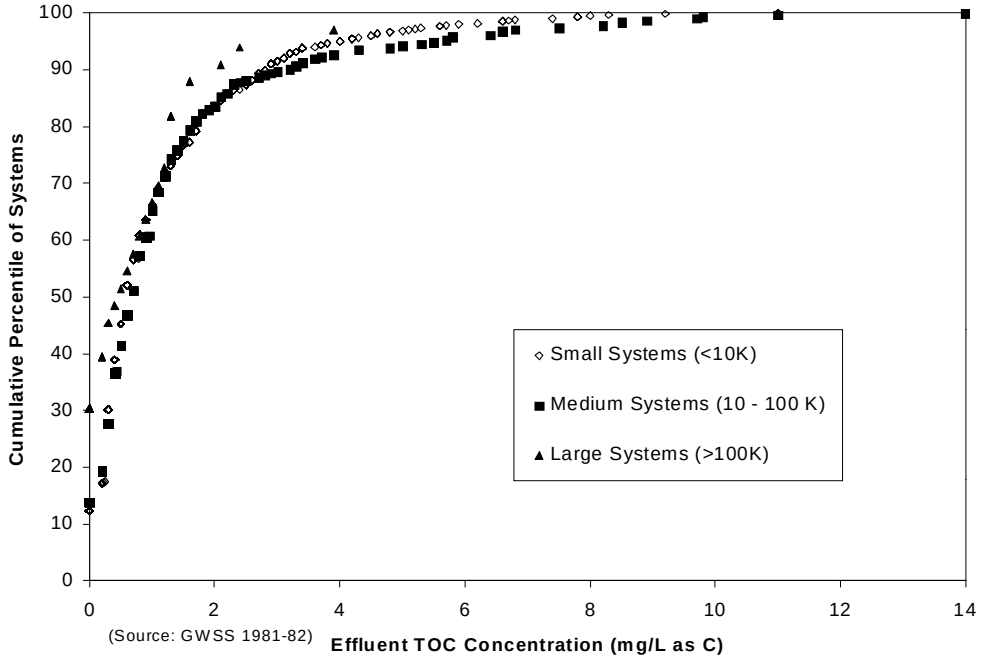
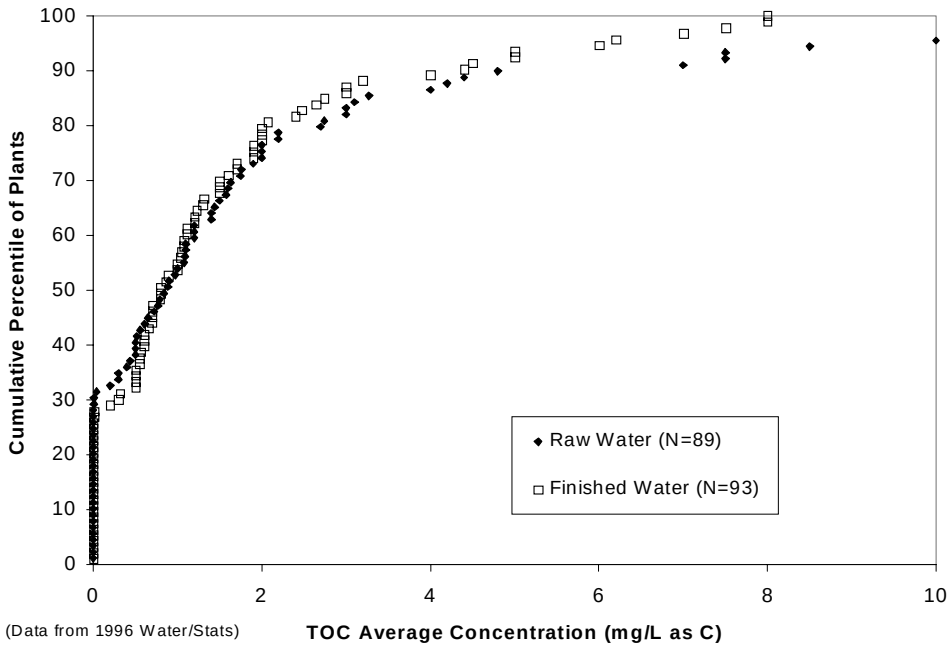
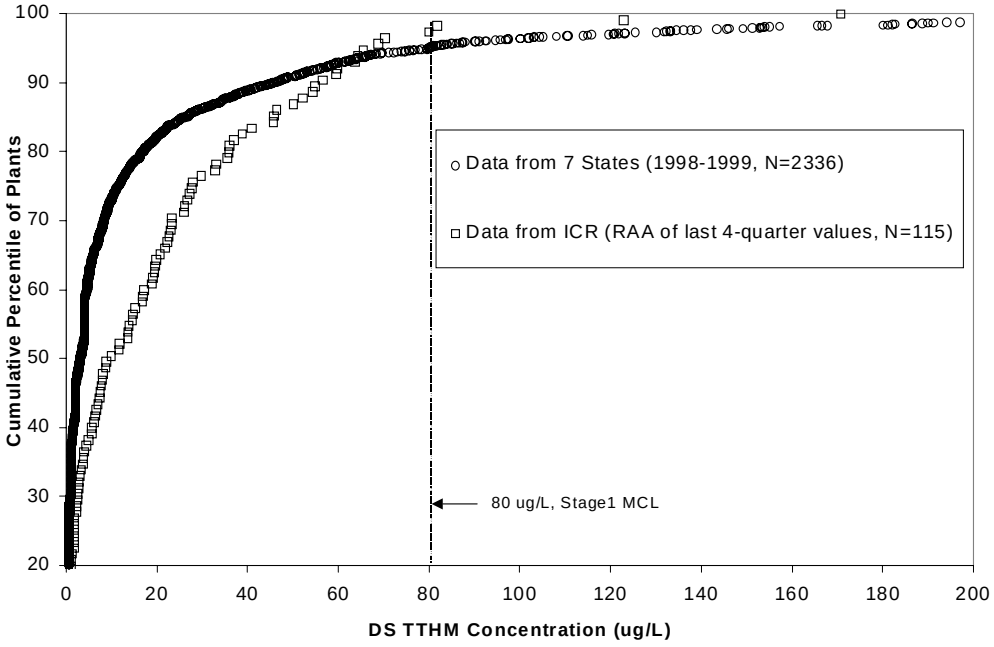


Figure IV.12. Source and Finished Water TOC Levels for Large & Medium Ground Water Systems.



Data on DBP occurrence for small ground water systems are also limited. Compiling the data from seven States leads to the observation that approximately 4.5 percent of small ground water systems, compared to 2 percent of ICR ground water systems, exceed the TTHM MCL of 0.080 mg/L (Figure IV.13).

Figure IV.13. TTHM Occurrence as Distribution System Average in Ground Water Systems.



C. Occurrence of other disinfection byproducts

1. Bromate

Bromate monitoring in the ICR was required at plants using ozone and chlorine dioxide. Bromate forms when these disinfectants react with bromide, a DBP surrogate precursor naturally present in many source waters. The cumulative probability distribution summary results for ICR influent bromide concentrations are presented in Table IV.4. (Section IV.B.1). Monthly bromate monitoring was required at the finished water sampling location since bromate formation does not increase with residence time in the absence of a chlorine dioxide or ozone residual. Neither of these disinfectants are used for residual disinfection in the distribution system.

The summary statistics of the last 12-month ICR monitoring results, January 1998 to December 1998, of the bromate samples analyzed by the EPA laboratory are shown in Table IV.8. Bromate concentrations as low as 0.2 μg/L could be quantified by the laboratory and this level was used as the minimum reporting level (MRL).

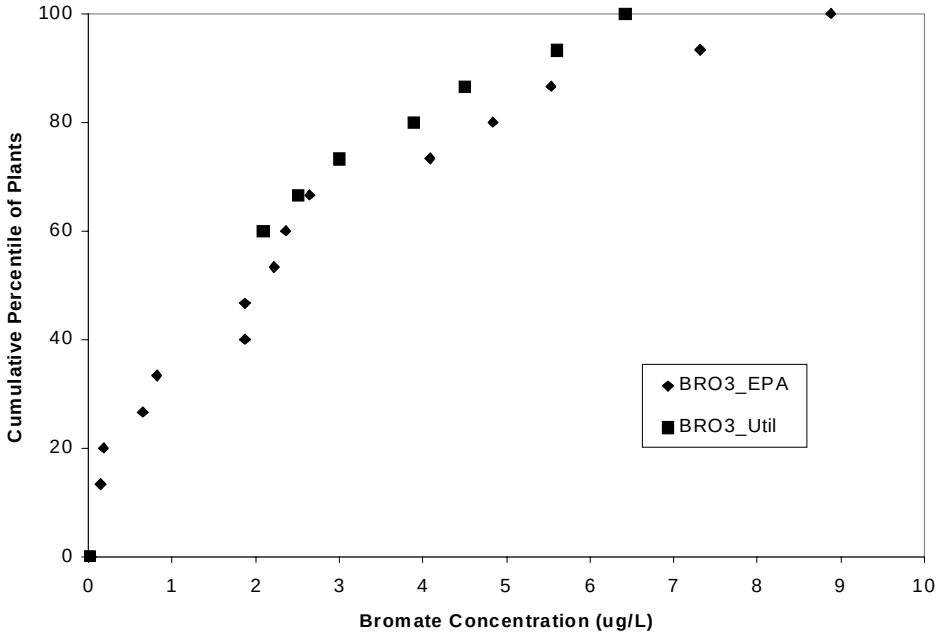
Table IV.8. Summary of ICR Bromate Concentrations in Finished Water.

Source	Number of Samples	Mean	Median	90th Percentile	Range
Disinfection with Chlorine Dioxide (concentrations in µg/L)					
Surface	199	0.06	<0.20	0.2	<0.20 - 2.38
Disinfection with Ozone (concentrations in µg/L)					
Surface	172	2.75	2.01	7.30	<0.20 - 14.6
Ground	12	<0.20	<0.20	0.48	<0.20 - 0.97

Finished = sample location after treatment, before entering the distribution system

For chlorine dioxide plants, the median was below 0.2 µg/L, and the 90th percentile was around 0.2 µg/L. This indicates that bromate formation is not an issue of concern for chlorine dioxide plants. For the ozone plants, the medians and 90th percentiles were below the MCL of 0.010 mg/L. The results reported in this table are for all reported values in the last 12-month monitoring. The running annual average bromate data for the same period are shown in Figure IV.14. This figure demonstrates reported results from 16 of the 20 ICR ozone plants for the monitoring period between January 1998 and December 1998 (Not all plants had sufficient data to calculate RAAs).

Figure IV.14. Cumulative Distribution of Bromate RAAs in Finished Water at ICR Ozone Plants.



The RAA for all ICR plants did not exceed the MCL of 0.010 mg/L for the duration of the ICR although some individual reported values exceeded the MCL, as shown in Table IV.8. Since the typical ozone doses used during the ICR were generally for taste and odor control and to achieve *Giardia* inactivation requirements (not for *Cryptosporidium* inactivation), EPA believes that in the future some plants will likely use higher ozone doses for the inactivation of *Cryptosporidium*, in response to LT2ESWTR requirements, which may result in higher bromate formation.

2. Other HAAs in addition to HAA5

The Stage 2 DBPR proposes to maintain the HAA5 MCL at 0.060 mg/L, measured as the sum of MCAA, DCAA, TCAA, MBAA and DBAA. The ICR required all plants to monitor a sixth HAA, bromochloroacetic acid (BCAA), and had optional monitoring for the other three HAAs (bromodichloroacetic acid (BDCAA), dibromochloroacetic acid (DBCAA) and tribromoacetic acid (TBAA)), which make up the HAA9 parameter. About 30 percent of the ICR plants reported HAA9 during the six monitoring quarters (out of 491 plants that reported HAA data, 110 surface waters and 47 ground waters reported HAA9).

The data shown in Table IV.9 is from Auxiliary 1, Version 5 (USEPA, 2000d), and is aggregated by source water category. The summary statistics from the cumulative probability distribution of the four quarters of distribution system data (median, 90^{th} percentiles and the range of the reported/calculated values) for HAA5 and HAA6 are presented in Table IV.9. The data are presented for the average of the four locations (DS Avg) and for the highest reported concentration (DS High) of the four distribution system locations for all ICR plants, given that all plants were required to report the concentration of BCAA. For this data analysis, data

screening is done such that only plants that had at least three distribution system locations and at least three quarters of data are included in the analysis. Plants included in the analysis have to have both HAA5 and HAA6 data so that the comparison can be made.

Table IV.9. A Comparison of HAA5 and HAA6 ICR Data.

Data Source	Median (µg/L)		90th Percentile (µg/L)		Range (µg/L)	
	HAA5	**HAA6**	**HAA5**	**HAA6**	**HAA5**	**HAA6**
Surface ***(246 plants)***						
DS Avg	24.8	28.0	53.0	56.0	0 - 114	0 - 117
DS High	40.8	46.0	84.0	94.0	0 - 188	0 - 192
Ground ***(95 plants)***						
DS Avg	2.6	2.8	21.5	28.0	0 - 70.8	0 - 79.5
DS High	6.3	8	45.4	50.1	0 - 124	0 - 135

The national data distributions for HAA5 and HAA6 are very similar with the addition of the concentration of BCAA resulting in only a few µg/L change in the reported class sums. While some plants that have high bromide concentrations in their source waters may see a significant impact from including the concentration of BCAA, the national distribution of the data and the summary statistics remained relatively the same. Therefore, there appears to be little advantage in using HAA6 instead of HAA5 as an indicator of HAA occurrence. The summary statistics for four quarters of HAA9 data are also shown in Table IV.10. For this data analysis, all the HAA9 data are used even if only two quarters of data were available. This was done because any data screening, other than the actual ICR validation, would have resulted in a very small data subset resulting in a weak statistical analysis.

Table IV.10. HAA9 distribution in a subset of ICR Plants that measured HAA9.

Data Source	Median (µg/L)	90th Percentile (µg/L)	Range (µg/L)
Surface ***(87 plants)***			
DS Average	30.0	66.0	0 - 117
DS High	42.4	90.0	0 - 185
Ground ***(41 plants)***			
DS Average	11.1	57.2	0 - 89.8
DS High	21.7	69.2	0 - 153

A comparison of the cumulative probability distribution summary statistics of the subset of ICR plants that measured HAA9 is shown in Table IV.11.

Table IV.11. Comparison of HAA5, HAA6 and HAA9 data in all plants that measured HAA9.

Summary Statistics	HAA5 (µg/L)	HAA6 (µg/L)	HAA9 (µg/L)
Range	0 - 166	0 - 176	0 - 185
Median	16.8	20.1	24.5
90th Percentile	50.0	56.1	64.0

The HAA9 median value is approximately 8 µg/L greater than the HAA5 median and the difference is higher (14 µg/L) for the 90th percentile. This indicates that HAA5 may be slightly underestimating the actual HAA concentration as measured by HAA9. Similar results are observed when the data are evaluated as plant means although the data are not presented in this section. While HAA9 may better represent the formation of this class of DBPs, particularly for high bromide waters, not all the laboratories have been able to measure all nine HAAs as seen by

only 30 percent of the ICR plants reporting their HAA9 concentrations. EPA, at this time, believes that HAA5 is a good surrogate for the HAA9 parameter.

3. Other organic ICR DBPs

In general, TTHM and HAA5 are considered surrogates for other organic disinfection byproducts. Another surrogate measure of halogenated organic byproducts is the total organic halogen (TOX) parameter. The ICR requirements gathered data for other identified DBPs that make up the summary parameter TOX. The DBPs monitored under the ICR include haloacetonitriles (HAN4), chloropicrin (CP), chloral hydrate (CH), the haloketones: 1,1-dichloropropanone (DCP) and 1,1,1- trichloropropanone (TCP), and cyanogen chloride (CNCl), monitored by plants using chloramines in the finished water and maximum distribution system location (data reported for the maximum residence time in the distribution system). The reported ranges are for all samples collected in the distribution system of all ICR plants. The sum of the halogen contributions of TTHM, HAAs and the above mentioned DBPs is included in the TOX parameter.

Table IV.12. Summary Statistics for Other ICR DBPs in All ICR Plants.

DBP[1]	Range	50th Percentile	90th Percentile
TOX (µg Cl^-/L)	<50 - 935	116	263
HAN4 (µg/L)	0 - 51.6	2.9	8.3
CH (µg/L)	<0.5 - 46	1.7	7.4
CP (µg/L)	<0.5 - 9.1	<0.5	0.8
DCP (µg/L)	<0.5 - 6.1	0.5	1.4
TCP (µg/L)	<0.5 - 12.8	0.8	3.1

Although the above reported concentration ranges are only for surface and ground water systems that serve $100,000, these DBPs are also expected to be formed in all chlorinated and chloraminated systems. As can be seen from the measured concentrations, these other ICR DBPs, measured as part of the TOX parameter, have very low levels and account for only 5 percent of TOX. Precursor removal treatment modifications that are used to decrease TTHM and HAA5 (which make up 20 to 50 percent of the TOX) should also decrease the concentrations of these DBPs. Therefore, EPA believes that these levels can be controlled by the standards that are set for TTHM and HAA5 and is expected to be accompanied by a decrease in TOX which would also result in lower exposure to the unknown fraction of the halogenated DBPs. EPA believes that the Stage 2 DBPR level reductions based on an LRAA standard will also protect against exposure to the unidentified DBP concentrations that may be of health concern. More detailed occurrence information for the other DBPs are reported in *Stage 2 Occurrence and Exposure Assessment for Disinfectants and Disinfection Byproducts* (USEPA, 2001b).

D. Predicted pre-Stage 2 DBPR occurrence baseline

The TTHM and HAA5 occurrence data summarized above is based on measured concentrations reported from various studies. Because byproduct measurement data from the ICR and other sources were collected prior to the implementation of the Stage 1 DBPR, they provide an "observed" characterization of the pre-Stage 1 conditions. To estimate the incremental impacts of the proposed Stage 2 DBPR, relative to the Stage 1 DBPR, it is necessary to predict how plants will modify their treatment processes to meet the requirements of both rules and to predict the byproduct occurrence levels resulting from those treatment process modifications. EPA used these predicted occurrence levels to estimate baseline DBP exposure and changes in exposure as part of an analysis of the benefits of the Stage 2 DBPR (USEPA, 2001d). This section discusses the methodology for developing occurrence predictions and presents the predicted pre-Stage 2 DBPR Occurrence distribution. The post-Stage 2 DBPR Occurrence predictions and the incremental reduction in byproduct levels are discussed in Section VII (Economic Analysis). Two aspects of the occurrence predictions should be emphasized:

- Quantitative predictions of treatment changes expected from compliance with the Stage 1 and Stage 2 DBPRs and resulting disinfection byproduct occurrence have been modeled for large surface water systems using the Surface Water Analytical Tool (SWAT), discussed below.
- Similar models are not available to predict treatment changes and resulting DBP occurrence in medium and small surface water plants, nor in ground water plants of any size. Therefore, the characterization of pre-Stage 2 DBPR treatment technologies for

these plants relied on expert judgement of pre-Stage 1 occurrence (presented above) and treatment data, and the SWAT modeled predictions for the large surface water systems. A discussion is provided of the expected occurrence of disinfection byproducts in these categories of systems relative to the predictions made for large surface water systems. Section VII (Economic Analysis) discusses the methodology for predicting treatment technologies in these systems.

1. Large and medium surface water systems

EPA developed predicted pre-Stage 1 occurrence estimates with the SWAT model used to predict pre-Stage 2 and post-Stage 2 DBPR occurrence. As discussed above, this was necessary to ensure that measurement of the impact of the Stage 1 and Stage 2 DBPRs, as characterized by changes in byproduct levels relative to current pre-Stage 1 conditions, reflected a common underlying set of assumptions. EPA used the SWAT to predict DBP occurrence levels in large surface water systems as part of the economic analysis for the Stage 2 DBPR (USEPA, 2001d). Data presented earlier in this section show that medium surface water plants are similar to large surface water plants with regard to influent water quality, treatment characterization, and DBP occurrence. Therefore, EPA has used the SWAT predictions to estimate national DBP occurrence levels in large and medium surface water systems.

A brief description of the SWAT and how it was used is provided below. A more detailed description of SWAT can be found in the *Economic Analysis for the Stage 2 DBPR* (USEPA, 2001).

The SWAT was developed to assist EPA in the Stage 2 DBPR development process. SWAT is a decision support computational model designed to predict the technologies that

would be selected for compliance with various rule options (i.e., Stage 1 DBPR and Stage 2 DBPR options) and resulting occurrence of DBPs. Within SWAT, there are three key components that work together to make these predictions. These are source water quality and process train data, the water treatment plant model (WTP model) and the Decision Tree program. The WTP model uses water quality parameters and process train data for a given plant to generate treated water quality predictions (for example, DBPs and disinfection performance criteria) for that plant. If the resulting DBP levels do not meet the user-defined compliance criteria (i.e., Stage 1 DBPR and Stage 2 options), then the Decision Tree program chooses the next least-cost treatment technology in the decision tree and the WTP model generates a new DBP prediction. This process continues until compliance is reached and the final DBP technologies and occurrence are output. SWAT's occurrence output contains plant predictions for the following distribution system values:

- Distribution System Average (DS Average): For each plant, the average DBP concentration in the distribution system is calculated based on the average distribution system residence time reported by the utility for each of ICR months 7 through 18 for which ICR data are available for that plant. These monthly values are then used to calculate an annual average for each plant.
- Distribution System Maximum (DS Maximum): For each plant, the highest DBP concentration in the distribution system is calculated based on the maximum distribution system residence time reported by the utility for each of ICR months 7 through 18 for which ICR data are available for that plant. These monthly values are then used to calculate an annual average for each plant.

SWAT was used in a three-step procedure to characterize the impacts of the Stage 2 DBPR alternatives: (1) model a pre-Stage 1 occurrence "baseline" using treatment plant and water quality characteristics from the ICR Auxiliary 1 database; (2) model pre-Stage 2 treatment technologies and occurrence to reflect modifications of baseline treatment plant characteristics needed to meet the Stage 1 DBPR; (3) model post-Stage 2 DBPR treatment technologies and occurrence to reflect modifications of baseline treatment plant characteristics needed to meet the Stage 2 DBPR option(s) being considered.

The SWAT modeling was carried out in this three step manner rather than in the seemingly more direct two-step sequence of Pre-Stage 1 to Pre-Stage 2, and then Pre-Stage 2 to Post-Stage 2 because of the complexities in modeling and the associated database that would be needed to store such data. SWAT produces good estimates of national treatment changes and exposure, but cannot be used for individual plant performance and DBP occurrence because of a large margin of error associated with individual plant predictions (versus the much smaller margin of error associated with national predictions). To determine the impacts of the Stage 2 DBPR both in terms of treatment changes and occurrence, the Stage 1 baseline is subtracted from the Stage 2 predictions outside of the SWAT. The predicted pre- Stage 1 and pre-Stage 2 DBPR TTHM and HAA5 occurrence is shown in Table IV.13. The statistics that are shown are annual plant-mean data (where annual data for each plant are averaged and statistics calculated from those means). This differs from the ICR statistics in Table IV.5. which are calculated from the distribution of the plant DS Average values (average of 4 distribution system samples) in each sample quarter.

Post-Stage 2 DBPR occurrence is discussed in Section VII (Economic Analysis). The *Economic Analysis for the Stage 2 Disinfectants and Disinfection Byproducts Rule* (USEPA, 2001d) provides a detailed description of the SWAT modeling process and the sensitivity of SWAT predictions.

Table IV.13. Predicted Annual Average DBP Occurrence Pre-Stage 1 and Pre-Stage 2 DBPR.

Parameter	Mean	Median	90th Percentile	Range
Total Trihalomethanes (TTHM) (Fg/L)				
Pre-Stage 1 DBPR	49	42	97	3 - 208
Pre-Stage 2 DBPR	35	36	57	3 - 64
HAA5 (Fg/L)				
Pre-Stage 1 DBPR	35	30	71	1 - 146
Pre-Stage 2 DBPR	25	25	41	1 - 48

2. Ground water systems and small surface water systems

The emphasis of the Stage 2 DBPR supporting analyses is on changes in treatment technologies required for compliance, and resulting reductions in DBP occurrence and exposure. Because the scope and nature of data available for ground water and small surface water systems are insufficient for the purpose of modeling DBP occurrence, EPA used alternative expert methods to estimate technology shifts. The Agency relied on predicted DBP occurrence for large surface water systems to develop national exposure estimates for populations served by all public water systems. The process for this analysis and relationships to the SWAT analysis described above are summarized in the following 3 steps.

Step 1 involved estimating Pre-Stage 1 DBPR average TTHM and HAA5 occurrence from available data. The following data were used for a baseline for the group of systems described:

- SWAT initial plant run for surface water systems serving at least 10,000 people;
- Surface water State data for surface water systems serving fewer than 10,000 people;
- ICR data for ground water systems serving at least 10,000 people; and

- Ground water State data for ground water systems serving fewer than 10,000 people.

In Step 2, EPA estimated the TTHM and HAA5 reduction achieved by the Stage 1 DBPR (Pre-Stage 2 DBPR). As discussed above, SWAT provides estimates of average TTHM and HAA5 occurrence following the Stage 1 DBPR for large and medium systems. In order to estimate exposure reductions, EPA also applied this distribution to small surface water systems. Percent reduction for surface waters was estimated as the difference between pre-Stage 1 estimates (Step 1) and pre-Stage 2 SWAT predicted values. SWAT results were also used as the basis for estimating reduction in occurrence for all ground water systems. The reduction was weighted to account for the difference between numbers of plants predicted to add treatment for surface and ground water systems.

Step 3 consisted of developing estimates of the TTHM and HAA5 reduction incurred by the Stage 2 DBPR (Post-Stage 2 DBPR) for each regulatory alternative and sensitivity analyses. As in step 2, SWAT was used to estimate percent reduction for all categories of systems. Ground water system reductions are adjusted to account for the lower percent of systems making treatment changes to comply with rule alternatives. Post-Stage 2 DBPR occurrence is presented in Section VII of this Federal Register notice.

The steps of this analysis are described in more detail in the *Economic Analysis for the Stage 2 Disinfectants and Disinfection Byproducts Rule* (USEPA, 2001d).

E. Request for comment

EPA requests comment on the analysis of DBP and DBP precursor occurrence data presented in section IV, on the assumptions made as a part of the analysis, and conclusions drawn from the analysis. EPA also requests additional occurrence data.

V. Discussion of Proposed Stage 2 DBPR Requirements

A. MCLG for chloroform

1. What is EPA proposing today?

EPA is proposing an MCLG for chloroform of 0.07 mg/L based on a cancer reference dose (RfD), an assumption that a person drinks 2 liters of water per day (the 90th percentile of intake rate for the U.S. population) and a relative source contribution (RSC) of 20 percent. The MCLG is proposed at a level at which no adverse effects on the health of persons is anticipated with an adequate margin of safety. This conclusion is based on toxicological evidence that the carcinogenic effects of chloroform are an ultimate consequence of sustained tissue toxicity. The MCLG is set at a daily dose for a lifetime at which no adverse effects will occur because the sustained tissue toxicity, which is a key event in the cancer mode of action of chloroform, will not occur. (USEPA, 2001f).

EPA believes that the RfD used for chloroform is protective of sensitive groups, including children. This RfD was developed by the EPA current method for developing RfDs based on animal data. The method is designed to be protective by taking human variability into account and assuming that the average human will be as sensitive as the most responsive animal species. Our understanding of the mode of action for chloroform does not indicate a uniquely sensitive subgroup or an increased sensitivity in children.

2. How was this proposal developed?

a. Background

EPA proposed a default zero MCLG for chloroform in the 1994 Stage 1 DBPR proposal (USEPA, 1994b). Following the proposal, numerous toxicological studies on chloroform were published and were discussed in two NODAs (USEPA, 1997; USEPA, 1998e). The 1998 NODA endorsed a nonlinear approach to chloroform risk assessment and requested comment on a chloroform MCLG of 0.3 mg/L. After considering comments on the NODAs, EPA determined that further deliberations with the SAB were needed before changing the MCLG for chloroform. Thus, EPA promulgated a chloroform MCLG of zero in the final Stage 1 DBPR (USEPA, 1998c) and committed to conducting additional deliberations with the SAB and factoring the SAB's review into the Agency's Stage 2 DBPR rulemaking process. The Agency consulted with the SAB in October 1999 (USEPA, 2000h).

The Stage 1 DBPR MCLG of zero for chloroform was challenged, and the U.S. Court of Appeals for the District of Columbia Circuit issued an order vacating the zero MCLG (Chlorine Chemistry Council and Chemical Manufacturers Association v. EPA, No. 98-1627 opinion filed March 31, 2000). The Court remanded the case to the Agency noting that EPA had committed to a new rulemaking which would propose and finalized a non-zero MCLG for chloroform (Chlorine Chemistry Council and Chemical Manufacturers Association v. EPA, No. 98-1627 (opinion filed June 27, 2000)). EPA removed the MCLG for chloroform from its NPDWRs (USEPA, 2000g). No other provision of the Stage 1 DBPR was affected.

b. Basis of the New Chloroform MCLG

The use of the best available science is a core EPA principle and is statutorily mandated by the 1996 SDWA Amendments. Based on an analysis of all the available scientific data on chloroform, EPA believes that chloroform dose-response is nonlinear and that chloroform is likely to be carcinogenic only under high exposure conditions. EPA's assessment of the cancer risk associated with chloroform exposure (USEPA, 2001f) uses the principles of the 1996 EPA Proposed Guidelines for Carcinogen Risk Assessment (USEPA, 1996c, 1999a).

Some stakeholders have objected to the Agency's use of the 1996 proposed guidelines. The 1996 Proposed Guidelines for Carcinogen Risk Assessment, as reviewed by the public and the EPA Science Advisory Board and revised in 1999, reflect new science and are consistent with, and an extension of, the existing 1986 Guidelines for Carcinogen Risk Assessment. The 1986 guidelines provide for departures from default assumptions such as low dose linear assessment. For example, the 1986 EPA guidelines reflect the position of the Office of Science and Technology Policy (OSTP) (1985; Principle 26) "No single mathematical procedure is recognized as the most appropriate for low-dose extrapolation in carcinogenesis. When relevant biological evidence on mechanisms of action exists (e.g, pharmacokinetics, target organ dose), the models or procedure employed should be consistent with the evidence." The 1986 guidelines go on to state "The Agency will review each assessment as to the evidence on carcinogenesis mechanisms and other biological or statistical evidence that indicates the suitability of a particular extrapolation model."

The EPA's 1996 Proposed Guidelines for Carcinogen Risk Assessment allow EPA to use default approaches to estimate cancer risk other than the historic, linearized multistage default

when there is an understanding of an agent's mode of carcinogenic action. EPA believes that the same conclusion on the carcinogenic risk from chloroform is reached whether it relies on the 1986 guidelines, the 1996 proposed guidelines, or the 1999 revisions.

i. Mode of action

EPA has fully evaluated the science on chloroform and concludes that chloroform is likely to be carcinogenic to humans under high exposure conditions that lead to cytotoxicity and regenerative hyperplasia in susceptible tissue; chloroform is not likely to be carcinogenic to humans at a dose level that does not cause cytotoxicity and cell regeneration (USEPA, 1998e, USEPA, 1998b, USEPA, 2001f).

Chloroform's carcinogenic potential is indicated by animal tumor evidence (liver tumors in mice and renal tumors in both mice and rats) from inhalation and oral exposure. Data on metabolism, toxicity, mutagenicity and cellular proliferation contribute to an understanding of the mode of carcinogenic action. For chloroform, sustained or repeated cytotoxicity with secondary regenerative hyperplasia precedes, and is a key event for, hepatic and renal neoplasia.

EPA believes that a DNA reactive mutagenic mode of action is not likely to be the predominant influence of chloroform on the carcinogenic process. EPA has concluded that the predominant mode of action involves cytotoxicity produced by the oxidative generation of highly reactive metabolites, followed by regenerative cell proliferation (USEPA, 2001e). EPA further believes that the chloroform dose-response is nonlinear. The SAB final report states "(t)he Subcommittee agrees with EPA that sustained or repeated cytotoxicity with secondary regenerative hyperplasia in the liver and/or kidney of rats and mice precedes, and is probably a causal factor for, hepatic and renal neoplasia" (SAB, 2000).

ii. Metabolism

The cytochrome P450 isoenzyme CYP 2E1 is the primary enzyme catalyzing chloroform metabolism at low concentrations. Chloroform's carcinogenic effects involve oxidative generation of reactive and toxic metabolites (phosgene and hydrochloric acid [HCl]) and thus are related to its noncancer toxicities (e.g., liver or kidney toxicities). The electrophilic metabolite phosgene could react with macromolecules such as phosphotidyl inositols or tyrosine kinases which in turn could potentially lead to interference with signal transduction pathways (i.e., chemical messages controlling cell division), thus leading to carcinogenesis. Likewise, it is also plausible that phosgene reacts with cellular phospholipids, peptides and proteins resulting in generalized tissue injury. Glutathione, free cysteine, histidine, methionine and tyrosine are all potential reactants for electrophilic agents.

At high concentrations, chloroform may undergo reductive metabolism which forms reactive dichloromethyl free radicals. These free radicals can contribute to lipid peroxidation and cause cytotoxicity.

c. How the MCLG is derived

EPA continues to recognize the strength of the science in support of a nonlinear approach for estimating the carcinogenicity of chloroform. This science was affirmed by the Chloroform Risk Assessment Review Subcommittee of the EPA SAB Executive Committee which met on October 27-28, 1999 (USEPA, 2000h). The SAB Subcommittee agreed that the nonlinear approach is most appropriate for the risk assessment of chloroform.

Nonzero MCLGs are scientifically and statutorily supported. The statute requires that the MCLG be set where no known or anticipated adverse effects occur, allowing for an adequate margin of safety (56 FR 3533; USEPA, 1991c). Historically, EPA established MCLGs of zero for known or probable human carcinogens based on the principle that any exposure to carcinogens might represent some finite level of risk. If there is substantial scientific evidence, however, that indicates there is a "safe threshold", then a nonzero MCLG can be established with an adequate margin of safety (56 FR 3533; USEPA, 1991b)).

EPA would ideally like to use the delivered dose (i.e., the amount of key chloroform metabolites that actually reach the liver and cause cell toxicity) for calculating an RfD to support the MCLG. However, the required toxicokinetic data are not currently available. Thus, the RfD is calculated using the applied dose (i.e., the amount of chloroform ingested). The RfD is based on both the benchmark dose and the traditional no observed adverse effect level/lowest observed adverse effect level (NOAEL/LOAEL) approaches for hepatotoxicity in the most sensitive species, the dog. The MCLG is based on the RfD and calculated as follows:

$$\textbf{MCLG} = \frac{\textbf{RfD x body weight x RSC}}{\textbf{daily water consumption}}$$

i. Reference dose

The RfD for chloroform was estimated based on noncancer effects using both the benchmark dose and the traditional NOAEL/LOAEL approaches. For benchmark analysis, five relevant data sets including target organ toxicity, labeling index, histopathology in rodents, and liver toxicity in dogs (Heywood, 1979) were evaluated. The effects seen in dogs are considered to be early signs of liver toxicity, preceding cytotoxicity, cytolethality and regenerative hyperplasia. Thus, the Heywood (1979) study, provides the most sensitive end point in the most sensitive species and is the most appropriate basis for the RfD.

The 95% confidence lower bound on the dose associated with a 10% extra risk (LED10) is based on the prevalence of animals demonstrating liver toxicity. After an exposure adjustment to the LED10 (1.2 mg/kg/day), an RfD of 0.01 mg/kg/day was calculated using an overall uncertainty factor of 100 (10 for interspecies extrapolation and 10 for protection of sensitive individuals) (USEPA, 2001e).

Coincidentally, the benchmark dose and the traditional NOAEL/LOAEL approaches yield the same RfD number (USEPA, 2001e). The NOAEL/LOAEL approach is also based on the Heywood study (1979) which had a LOAEL of 15 mg/kg/day for evidence of liver toxicity. After an exposure adjustment to the LOAEL (yielding 12.9 mg/kg/day), an RfD of 0.01 mg/kg/day was calculated using an overall uncertainty factor of 1000 (10 for interspecies extrapolation, 10 for protection of sensitive individuals, and 10 for using a LOAEL instead of a NOAEL) (USEPA, 2001e).

The RfD is also equal to the Agency for Toxic Substances and Disease Registry 's (ATSDR) minimal risk level (Toxicological Profile, 1996) and the World Health Organization's tolerable daily intake (TDI) (WHO, 1998), which are also based on the Heywood (1979) study.

ii. Relative source contribution

Another factor in determining the MCLG is the relative source contribution (RSC). The RSC is used when the MCLG is set at a level above zero. Its purpose is to ensure that the contribution to exposure from drinking tap water does not cause the lifetime daily exposure of persons to a contaminant to exceed RfD. The RSC is thus, a factor used to make sure that the MCLG is protective even if persons are exposed to the contaminant by other routes (inhalation, dermal absorption) or other sources (e.g., food). If sufficient quantitative data are not available on exposure by other routes and sources, EPA has historically assumed that the RSC from drinking water is 20 percent of the total exposure, a value considered protective. If data indicate that contributions from other routes and sources are not significant, EPA has historically assumed a somewhat less conservative RSC of 80 percent (54 Fed. Reg. 22,062, 22,069 (May 22, 1989)(USEPA, 1989a), 56 Fed. Reg. at 3535 (Jan 30, 1990)(USEPA, 1991b), 59 Fed. Reg. 38,668, 38,678 (July 29, 1994)(USEPA, 1994b)).

Today, EPA is proposing an assumption of a 20 percent RSC. This is in consideration of data which indicate that exposure to chloroform by other routes and sources of exposure may potentially contribute a substantial percentage of the overall exposure to chloroform.

In the 1998 Stage 1 DBPR NODA, EPA considered an MCLG of 0.3 mg/L that was calculated using a RSC of 80 percent, based on the assumption that most exposure to chloroform is likely to come from ingestion of drinking water. In the final Stage 1 DBPR, EPA reconsidered

this assumption in response to comments and in the light of data which indicate that exposure to chloroform by inhalation and dermal exposure may potentially contribute a substantial percentage of the overall exposure to chloroform depending on the activity patterns of individuals (USEPA, 1998) e.g., during showering, bathing, swimming, boiling water, clothes washing, and dishwashing. There is also potential exposure to chloroform by the dietary route. There are uncertainties regarding other possible highly exposed sub-populations, e.g., swimmers, those who use humidifiers, hot-tubs, and outdoor misters, persons living near industrial sources, people working in laundromats, and persons working with pesticides employing chloroform as a solvent (USEPA, 1998b).

A 1998 ILSI report evaluated the uptake of drinking water contaminants through the skin and by inhalation. The report noted that "(i)n the case of chloroform, its high volatility leads to its rapid movement from liquid to air. Large water-use sources, such as showers, become dominant sources with respect to exposure" and "(t)he inhalation route is demonstrated to be the primary route for higher-volatility compounds (e.g., chloroform)" (ILSI, 1998). Weisel and Jo (1996) found that "approximately equivalent amounts of chloroform from water can enter the body by three different exposure routes, inhalation, dermal absorption, and ingestion, for typical daily activities of drinking and bathing."

Chloroform has been found in beverages, especially soft drinks, and food, particularly dairy products (Wallace, 1997). Wallace states that "ingestion (drinking tap water and soft drinks and eating certain dairy foods), inhalation (breathing peak amounts of chloroform emitted during showers or baths, and lower levels in indoor air from other indoor sources), and dermal

absorption (during showers, baths, and swimming)" each "appear to be potentially substantial contributors to total exposure".

EPA estimates that for the median individual, ingestion of total tap water (assuming certain activity patterns, habits, and home characteristics) can contribute roughly 28 percent of the total dose of chloroform (USEPA, 2001a). With assumptions as described, tap water ingestion is a portion of exposure through fluid intake which contributes about 34 percent of the total dose, inhalation accounts for about 31 percent of the total dose, ingestion of foods contributes another 27 percent of the overall dose, and dermal absorption (primarily during showering) adds slightly less than 8 percent of the total dose. These exposure percentages are based on average daily doses (mean chloroform intake for adults) for each source and route of exposure under specific conditions. They do not take into account the considerable variability in several factors across the population. For instance, intake of drinking water or particular foods and length of shower varies from day-to-day, as do home air turnover rates and ventilation. Different areas in the United States vary with respect to these factors and chloroform concentrations in food. Thus, although the 28 percent for the median individual is based on reasonable assumptions, uncertainty remains.

Given the uncertainties of estimation, EPA believes available analyses point to the RSC of 20 percent as the appropriate default. EPA also believes that this default is protective of public health and is a more reasonable choice than choosing any particular estimate because of large numbers of assumptions and uncertainties involved which each estimation. Hence, EPA is proposing the MCLG based on the RSC default of 20 percent which supports the adequacy of the margin of safety associated with the MCLG.

iii. Water ingestion and body weight assumptions

In MCLG calculations, EPA assumes the 90th percentile water ingestion of 2 liters (roughly equivalent to a half gallon) per day (USEPA, 2000b). The use of a conservative consumption estimate is consistent with the objective of setting an MCLG that is protective. EPA also uses a default adult body weight of 70 kg (equal to 154 pounds) for the RfD since dose is calculated from lifetime studies of animals and compared to lifetime exposure for humans.

iv. MCLG calculation

The MCLG is calculated to be 0.07 mg/L using the following assumptions: an adult tap water consumption of 2 L per day for a 70 kg adult, and a relative source contribution of 20 %:

$$\textbf{MCLG for Chloroform} = \frac{\textbf{0.01 mg/kg/d x 70 kg x 0.2}}{\textbf{2L/day}} = \textbf{0.07 mg/L(rounded)}$$

EPA concludes that an MCLG of 0.07 mg/L based on protection against liver toxicity will be protective against carcinogenicity given that the mode of action for chloroform involves cytotoxicity as a key event preceding tumor development. Therefore, the recommended MCLG for chloroform is 0.07 mg/L.

v. Other considerations

The evidence supports similarity of potential response in children and adults. The basic biology of toxicity caused by cell damage due to oxidative damage is expected to be the same. There is nothing about the incidence and etiology of liver and kidney cancer in children to indicate that they would be inherently more sensitive to this mode of action. Most importantly in this case, children appear to be no different quantitatively in ability to carry out the oxidative metabolism step for the induction of toxicity and cancer and may, as fetuses, be less susceptible (USEPA, 1999d).

Some commenters on the March 1998 NODA were concerned that EPA did not take drinking water epidemiology studies into account in its evaluation of chloroform risk. EPA believes that while the epidemiologic evidence that chlorinated drinking water may be associated with certain cancers and reproductive/developmental effects is pertinent to the risk of disinfectant byproduct mixtures, it does not provide insight into the risk from chloroform specifically. The SAB noted that "(t)he goal of the draft risk assessment (the isolation of the effect of chloroform in drinking water) makes the extensive epidemiologic evidence on drinking water disinfection byproducts largely irrelevant" to the question of chloroform health risks because chloroform cannot be isolated from other disinfection byproducts (SAB, 2000). The SAB noted that "the epidemiologic evidence is quite pertinent to the broader question of most direct regulatory concern, namely disinfection byproducts in the aggregate".

d. Feasibility of other options

During the development of the MCLG for chloroform, EPA considered a number of options for both the chloroform MCLG and the TTHM MCL. Today, EPA is proposing the preferred option of a 0.070 mg/L MCLG for chloroform. EPA primarily considered two other options which are discussed in more detail below: a 0.070 mg/L MCLG for chloroform in conjunction with developing MCLs for each of the individual TTHMs (i.e., 4 MCLs and 4 MCLGs for the THMs); and developing a single combined MCLG for TTHM rather than developing a separate MCLG for each of the THMs.

EPA considered developing separate MCLGs and MCLs for each THM. Under this strategy, EPA would determine an MCL as close to the individual MCLGs as is technically feasible, taking cost into consideration, for each THM. EPA would propose an MCLG of 0.070

mg/L for chloroform and maintain the Stage 1 DBPR MCLGs for BCDM, DBCM, and bromoform (USEPA, 1998c). EPA analyzed the impact such an MCL strategy would have and ultimately rejected this option. This approach represents a fundamental shift from the TTHM strategy agreed to by stakeholders and EPA as part of the M-DBP negotiation process and reflected in the 1998 Stage 1 DBPR. In addition, one important component of the existing single MCL is that TTHM are an indicator for other DBPs. Developing a separate MCL for each THM would move away from this indicator approach. Because precursor and DBP occurrence measurements are highly variable, both temporally and geographically, determining technical feasibility for BAT would be difficult. Compliance with individual THM standards would be very different from compliance based on a sum of the four THMs and it is possible that major industry technology shifts would be needed. This problem would be particularly exacerbated in areas with high bromide, such as California. EPA also projected that States would have a difficult time overseeing (e.g., variances, exemptions, etc.) the more complicated rule that would result from this option.

EPA considered establishing a single combined MCLG for TTHM. There is precedent for establishing a total equivalents approach (analogous to a combined MCLG) for dioxin and coplanar PCBs (US EPA, 2001, Draft Dioxin Assessment). From a scientific standpoint, a combined MCLG approach requires that the chemicals have a similar mode of action and health endpoint. Chemicals within each of the dioxin and coplanar PCB classes have the same mode of action and endpoint (target tissue). Within the PCB class, noncoplanar PCBs have a different mode of action than the coplanar PCBs. Noncoplanar PCBs are, therefore, not included in the TEQ for coplanar PCBs. EPA believes that the THMs have different modes of action and health

endpoints. One of the THMs is a liver carcinogen (chloroform) with a mode of action dependent on cytolethality; two are DNA-reactive carcinogens (bromodichloromethane - large intestine and kidney tumors, and bromoform - large intestine tumors); and one is a nonlinear non-carcinogen (dibromochloromethane) which is a liver toxicant. EPA therefore, chose not to develop a combined MCLG for TTHM.

In conclusion, after considering the options discussed above, EPA chose to propose an MCLG of 0.07 mg/L for chloroform and to continue to regulate TTHM as a group with a single MCL and separate MCLGs.

3. Request for comment

Based on the information presented above, EPA is proposing an MCLG for chloroform of 0.07 mg/L. EPA requests comments on the MCLG and on EPA's cancer assessment for chloroform. EPA also requests comments on the RfD, the default RSC of 20 percent, and the tap water consumption and body weight assumptions used in the MCLG calculation. EPA solicits additional data on chloroform exposure via other sources and routes. EPA requests comment on the other options for developing the chloroform MCLG that the Agency considered.

B. MCLGs for THMs, HAAs, and bromate

1. What is EPA proposing today?

Today EPA is proposing new MCLGs of 0.08 mg/L for TCAA and 0.1 mg/L for MCAA. As a part of the Stage 1 DBPR, EPA finalized an MCLG of 0.3 mg/L for TCAA. The Stage 1 DBPR did not include an MCLG for MCAA. With the exception of these HAAs and chloroform, discussed above, EPA is not revising any of the other MCLGs that were finalized in the Stage 1 DBPR. No significant new studies that would change EPA's MCLG estimates for

BDCM, DBCM, bromoform, DCAA, or bromate have been published since the Stage 1 DBPR. See section III for a summary of new health effects data.

2. How was this proposal developed?

EPA reviewed the available literature on BDCM, DBCM, bromoform, DCAA, and bromate and determined that there was no new information that would cause EPA to revise its MCLG estimates. New toxicology studies on reproductive and developmental effects and cancer are summarized in sections III.B. and III.D. of today's proposal.

EPA is proposing new MCLGs for TCAA and MCAA. The health effects information and studies described in the following two sections, that support the proposed MCLGs, are summarized from the Draft Drinking Water Criteria Document for Monochloroacetic Acid and Trichloroacetic Acid (USEPA, 2000a). The occurrence of HAAs is discussed in section IV and the occurrence of MCAA and TCAA are discussed in the *Draft Stage 2 Disinfectants/Disinfection Byproducts Occurrence and Exposure Document* (USEPA, 2001b).

a. Trichloroacetic acid

In the final Stage 1 DBPR, EPA based its assessment of TCAA health effects on developmental toxicity and limited evidence of carcinogenicity (USEPA, 1998). Since then, the Agency has decided that the RfD based on a developmental LOAEL yields a less conservative RfD than one based on liver toxicity derived from the study by DeAngelo et.al (1997). Thus, the Agency has reassessed the health effects of TCAA based on liver toxicity and revised the RfD and MCLG.

TCAA induces systemic, noncancer effects in animals and humans that can be grouped into three categories: metabolic alterations, liver toxicity; and developmental toxicity. The primary site of TCAA toxicity is the liver (U.S. EPA, 1994; Dees and Travis, 1994; Acharya et al., 1995; Acharya et al., 1997; DeAngelo et al, 1997).

The liver has consistently been identified as a target organ for TCAA toxicity in short-term (Goldsworthy and Popp, 1987; DeAngelo et al., 1989; Sanchez and Bull, 1990) and longer-term (Bull et al., 1990; Mather et al., 1990; Bhat et al., 1991) studies. Peroxisome proliferation has been a primary endpoint evaluated, with mice reported to be more sensitive to this effect than rats. More recent studies have confirmed these earlier findings. TCAA induced peroxisome proliferation in B6C3F1 mice exposed for 10 weeks to doses as low as 25 mg/kg/day (Parrish et al., 1996), while in rats exposed to TCAA for up to 104 weeks (DeAngelo et al.,1997), peroxisome proliferation was observed at 364 mg/kg/day, but not at 32.5 mg/kg/day. Increased liver weight and significant increases in hepatocyte proliferation have been observed in short-term studies in mice at doses as low as 100 mg/kg/day (Dees and Travis, 1994), but no increase in hepatocyte proliferation was noted in rats given TCAA at similar doses (DeAngelo et

al., 1997). More clearly adverse liver toxicity endpoints, including increased serum levels of liver enzymes (indicating leakage from cells) or histopathological evidence of necrosis, have been reported in rats, but generally only at high doses. For example, in a rat chronic drinking water study, increased hepatocyte necrosis was observed at a dose of 364 mg/kg/day (DeAngelo et al., 1997).

In the DeAngelo et al. (1997) study, groups of 50 male F344 rats were administered TCAA in drinking water (pH adjusted to 6.9 - 7.1), at 0, 50, 500, or 5000 mg/L, resulting in time-weighted mean daily doses of 0, 3.6, 32.5, or 364 mg/kg for 104 weeks, beginning at 28-30 days of age. Interim sacrifices were conducted at 15, 30, 45, and 60 weeks; terminal sacrifice was at 104 weeks. There were no significant differences in water consumption or survival between the control and treatment groups. Exposure to the high dose of TCAA resulted in a significant decrease in body weight of 11% at the end of the study. The absolute, but not relative liver weight, was decreased at the high dose. Complete necropsy and histopathology examination showed mild hepatic cytoplasmic vacuolization in the two low-dose groups, but not in the high dose group. The severity of hepatic necrosis was increased mildly in the high-dose animals. Analyses of serum aspartate aminotransferase (AST) and alanine aminotransferase (ALT) activities at the end of exposure showed a significant decrease in AST activity in the mid-dose group and a significant increase in ALT level in the high-dose group. Since increased serum ALT or AST levels reflect hepatocellular necrosis, the increased ALT at the high dose is considered an adverse effect, while a non-dose related decrease of AST is not. Peroxisome proliferation was increased significantly in the high dose animals. There was no evidence of any exposure-related increase in hepatocyte proliferation. Based on the significant decrease in body

weight ($10%), minimal histopathology changes, and increased serum ALT level, the high dose of 364 mg/kg/day is considered the LOAEL and the mid dose of 32.5 mg/kg/day is considered the NOAEL.

There are no reproductive toxicity studies of TCAA The results of an *in vitro* fertilization assay indicated that TCAA might decrease fertilization (Cosby and Dukelow, 1992). The available data suggest that TCAA is a developmental toxicant. TCAA increased resorptions, decreased implantations, and increased fetal cardiovascular malformations when administered to pregnant rats at 291 mg/kg/day (Johnson et al., 1998) on gestation days 1-22. In another study, decreased fetal weight and length, and increased cardiovascular malformations were observed when pregnant rats were administered 330 mg/kg/day TCAA by gavage during gestation days 6 to 15 (Smith et al., 1989). Neither of these studies identified a NOAEL. The results of *in vitro* developmental toxicity assays, including mouse and rat whole-embryo culture (Saillenfait et al., 1995; Hunter et al., 1996) and frog embryo teratogenesis assay - *Xenopus* (FETAX) (Fort et al., 1993) yielded postive results. But the *Hydra* test system (Fu et al., 1990) produced negative results.

TCAA was reported to induce liver tumors in mice but not in rats (U.S. EPA, 1994). This observation has also been made in more recent drinking water studies. Pereira (1996) observed an increased incidence of hepatocellular adenomas and carcinomas in female B6C3F1 mice at doses of 262 mg/kg/day and higher after 82 weeks. In contrast, no increase in neoplastic liver lesions were found in F344 rats given doses up to 364 mg/kg/day for 104 weeks (DeAngelo et al., 1997). In addition, a variety of recent mechanistic studies have observed that TCAA either

induced or promoted liver tumors in mice (Ferreira-Gonzalez et al., 1995; Pereira and Phelps, 1996; Tao et al., 1996; Latendresse and Pereira, 1997; Stauber and Bull, 1997; Tao et al., 1998).

Recent mutagenicity data have provided mixed results (Giller et al., 1997; DeMarini et al., 1994; Harrington-Brock et al., 1998). TCAA did not induce oxidative DNA damage in mice following dosing for either 3 or 10 weeks (Parrish et al., 1996). Studies on DNA strand breaks and chromosome damage produced mixed results (Nelson and Bull, 1988; Chang et al., 1991; Mackay et al., 1995; Harrington-Brock et al., 1998).

Following the EPA's 1986 Guidelines for Carcinogen Risk Assessment (U.S. EPA, 1986) TCAA is best classified as Group C: Possible Human Carcinogen, based on limited evidence (increase in liver tumors in mice only). According to the 1999 Draft Guidelines for Carcinogen Risk Assessment (U.S. EPA, 1999), a compound is appropriately classified as "Suggestive Evidence of Carcinogenicity, but Not Sufficient to Assess Human Carcinogenic Potential" when "the evidence from human or animal data is suggestive of carcinogenicity, which raises a concern for carcinogenic effects but is judged not sufficient for a conclusion as to human carcinogenic potential". Based on uncertainty surrounding the relevance of the liver tumor data in B6C3F1 mice, TCAA can best be described as "Suggestive Evidence of Carcinogenicity, but Not Sufficient to Assess Human Carcinogenic Potential" under the 1999 Draft Guidelines for Carcinogen Risk Assessment. Thus a quantitative estimate of cancer potency is not supported.

The RfD for TCAA of 0.03 mg/kg/day is based on the NOAEL of 32.5 mg/kg/day for liver histopathological changes identifed by DeAngelo et al. (1997). There is an uncertainty factor of 1000 (composite uncertainty factor consisting of three factors of 10 chosen to account for extrapolation from a NOAEL in animals, inter-individual variability in humans, and

insufficiencies in the database, including the lack of full histopathological data in a second species, the lack of a developmental toxicity study in second species, and the lack of a multi-generation reproductive study). Two developmental toxicity studies (Smith et al., 1989; Johnson et al., 1998) identified developmental LOAELs for rats in drinking water and by gavage of 291 and 330 mg/kg/day, respectively. The developmental study by Smith et al. (1989) was used to derive the RfD in the draft criteria document (U.S. EPA, 1994) which was the basis of the Stage 1 DBPR MCLG (USEPA, 1998). The developmental LOAEL yields a less conservative RfD than the one based on liver toxicity. Thus the study by DeAngelo et.al (1997) is more appropriate for derivation of the RfD and MCLG.

The MCLG is calculated to be 0.02 mg/L using the following assumptions: an adult tap water consumption of 2 L of tap water per day for a 70 kg adult, a relative source contribution (RSC) of 20 %, and an additional safety factor to account for possible carcinogenicity.

$$\textbf{MCLG for TCAA} = \frac{\textbf{(0.03 mg/kg/day)(70 kg)(20\%)}}{\textbf{(2 L/day) (10)}} = \textbf{0.02 mg/L (rounded)}$$

A RSC factor of 20% is used to account for exposure to TCAA in other sources in addition to tap water, such as ambient air and food. Although TCAA is nonvolatile and inhalation while showering is not expected to be a major contribution to total dose, rain waters contain 0.01- 1.0 Fg/L of TCAA (Reimann and Grob, 1996) and it can be assumed detected TCAA is from the atmosphere. Limited data on concentrations of TCAA in air (NATICH, 1993) indicate inhalation of TCAA in ambient air may contribute significantly to overall exposure. Concentrations of TCAA that have been measured in a limited selection of foods including vegetables, fruits, grain and bread (Reimann and Grob, 1996) are comparable to that in water.

About 3 to 33% of TCAA in cooking water have been reported to be taken up by the food during cooking in a recent research summary (USEPA, 2001). In addition, there are uses of chlorine in food production and processing, and TCAA may occur in food as a byproduct of chlorination (USEPA, 1994). Therefore, ingestion of TCAA in food may also contribute to the overall exposure. A recent dermal absorption study of DCAA and TCAA from chlorinated water suggested that the dermal contribution to the total doses of DCAA and TCAA from routine household uses of drinking water is less than 1% (Kim and Weisel,1998).

b. Monochloroacetic acid

Subchronic and chronic oral dosing studies suggest that the primary targets for MCAA-induced toxicity include the heart and nasal epithelium. In a 13-week oral gavage study, decreased heart weight was observed at 30 mg/kg/day and cardiac lesions progressed in severity with increasing dose. Liver and kidney toxicity were only observed at higher doses (NTP, 1992). In a two-year study, decreased survival and nasal and forestomach hyperplasia were observed in mice at 50 mg/kg/day (NTP, 1992). A more recent study confirms the heart and nasal cavities as target sites for MCAA. DeAngelo et al. (1997) noted decreased body weight at 26.1 mg/kg/day and myocardial degeneration and inflammation of the nasal cavities in rats exposed to doses of 59.9 mg/kg/day for up to 104 weeks.

No studies were located on the reproductive toxicity of MCAA and the potential developmental toxicity of MCAA has not been adequately tested. Two developmental toxicity studies were identified. Johnson et al. (1998) reported markedly decreased maternal weight gain, but no developmental effects, in rats exposed to 193 mg/kg/day MCAA through gestation days 1-22, only fetal heart was examined. In contrast, in a published abstract, Smith et al. (1990)

reported an increase in cardiovascular malformations when pregnant rats exposed to 140 mg/kg/day; this was also the LOAEL for maternal toxicity, based on marked decreases in weight gain. MCAA was noted as a potential developmental toxicant in *in vitro* screening assays using *Hydra* (Fu et al., 1990; Ji et al., 1998).

MCAA has yielded mixed results in genotoxicity assays (U.S. EPA, 1994; Giller et al, 1997), but has not induced a carcinogenic response in chronic rodent bioassays (NTP, 1992; DeAngelo et al., 1997). In chronic oral gavage studies, a LOAEL of 15 mg/kg/day (the lowest dose tested) for decreased survival was identified in rats. In mice the NOAEL was 50 mg/kg/day and the LOAEL was 100 mg/kg/day for nasal and forestomach epithelium hyperplasia (NTP, 1992). In a more recent chronic study, DeAngelo et al. (1997) reported a LOAEL of 3.5 mg/kg/day in rats given MCAA in their drinking water, based on increased absolute and relative spleen weight. Although spleen weight was decreased at the mid and high doses, this might reflect the masking effect of overt toxicity. As evidence for this, decreased body weight (>10%), liver, kidney, and testes weight changes were reported beginning at the next higher dose of 26.1 mg/kg/day. No increased spleen weight was reported in the NTP (1992) bioassays, but the lowest dose in rats caused severe toxicity, and the lowest dose in mice was more than an order of magnitude higher than the LOAEL in the DeAngelo et al. (1997) study.

Following the EPA's 1986 Guidelines for Carcinogen Risk Assessment (U.S., EPA, 1986), MCAA is best classified as Group E: Evidence for Non-Carcinogenicity for Humans, based on the absence of carcinogenicity in well-conducted studies in two different species given MCAA by the relevant route of exposure (NTP, 1992; DeAngelo et al., 1997). According to the 1999 Draft Guidelines for Carcinogen Risk Assessment (U.S. EPA, 1999), a compound is

appropriately classified as “Not Likely to be Carcinogenic to Humans” when it has “been evaluated in as least two well-conducted studies in two appropriate animal species without demonstrating carcinogenic effects.” MCAA can best be described as “Not Likely to be Carcinogenic to Humans” under the 1999 Draft Guidelines for Carcinogen Risk Assessment.

The RfD for MCAA of 0.004 mg/kg/day is based on a LOAEL of 3.5 mg/kg/day for increased spleen weight in rats (DeAngelo et al., 1997) and application of an uncertainty factor of 1000 (composite uncertainty factor consisting of two factors of 10 chosen to account for extrapolation from an animal study, and inter-individual variability in humans; as well as two factors of 3 for extrapolation from a minimal effect LOAEL, and insufficiencies in the database, including the lack of adequate developmental toxicity studies in two species, and the lack of a multi-generation reproductive study). Two developmental toxicity studies have been reported (Johnson et al., 1998; Smith et al., 1990), but the NOAELs yielded less conservative RfDs. The study by DeAngelo et al (1997) is the most appropriate for derivation of the RfD because it identifies the lowest LOAEL, and dosing was in drinking water, which is more appropriate for human health risk assessment.

The MCLG is calculated to be 0.03 mg/L using the following assumptions: an adult tap water consumption of 2 L of tap water per day for a 70 kg adult, and a relative source contribution of 20 %.

$$\textbf{MCLG for MCAA} = \frac{\textbf{(0.004 mg/kg/day)(70 kg)(20\%)}}{\textbf{(2 L/day)}} = \textbf{0.03 mg/L (rounded)}$$

A RSC factor of 20% is used to account for exposure to MCAA in other sources in addition to tap water. Although MCAA is nonvolatile and inhalation while showering is not

expected to be a major contribution to total dose, rain waters contain 0.05- 9 Fg/L of MCAA (Reimann and Grob, 1996) and it can be assumed detected MCAA is from the atmosphere. The range of MCAA concentrations in rain waters is higher than that for TCAA. Thus, inhalation of MCAA in ambient air may contribute significantly to overall exposure. Concentrations of MCAA that have been measured in a limited selection of foods including vegetables, fruits, grain and bread (Reimann and Grob, 1996) are comparable to that in water. About 2.5 to 62% of MCAA in cooking water have been reported to be taken up by the food during cooking in a recent research summary (USEPA, 2001). In addition, there are uses of chlorine in food production and processing, and MCAA may occur in food as a byproduct of chlorination (USEPA, 1994). Therefore, ingestion of MCAA in food may also contribute to the overall exposure. Assuming dermal absorption rate of MCAA is similar to DCAA, dermal contribution to the total doses of MCAA from routine household uses of drinking water should be minor (see V.B.2.a.).

3. Request for comment

EPA requests comment on the new MCLGs for TCAA (0.02 mg/L) and MCAA (0.03 mg/L) and all the factors incorporated in the derivation of the MCLGs, including the RfDs and RSCs. EPA also solicits health effect information on DBAA and MBAA, for which MCLGs have not yet been established, and requests comment on maintaining the Stage 1 DBPR MCLGs for BDCM, DBCM, bromoform, DCAA, and bromate.

C. MCL and BAT for TTHM and HAA5

1. What is EPA proposing today?

Today, EPA is proposing phased MCLs for TTHM and HAA5 as recommended by the Stage 2 M-DBP Advisory Committee. The Advisory Committee made this recommendation in order to maintain parallel rule compliance schedules for the Stage 2 DBPR and the LT2ESWTR. EPA determined that the recommendation was appropriate as a means of complying with statutory requirements for risk balancing (Section 1412(b)(5)). In Stage 2 A, all systems must comply with transition MCLs of 0.120 mg/L TTHM and 0.100 mg/L HAA5 as LRAAs using Stage 1 DBPR compliance monitoring sites. In addition, during this time period, all systems must continue to comply with the Stage 1 DBPR MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as an RAA. In Stage 2 B, systems must comply with long-term MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as LRAAs based on new sampling sites identified under the IDSE. Details of proposed monitoring requirements and compliance schedules are discussed in preamble sections V.F. and V.G., respectively and in §141.10xx of today's rule.

Today, EPA is proposing the BAT for the TTHM and HAA5 LRAA MCLs (0.080 mg/L and 0.060 mg/L respectively) as one of the three following technologies with chlorine as the primary and residual disinfectant:

- GAC adsorbers with at least 10 minutes of empty bed contact time and an annual average reactivation/replacement frequency no greater than 120 days.
- GAC adsorbers with at least 20 minutes of empty bed contact time and an annual average reactivation/replacement frequency no greater than 240 days.

- Nanofiltration using a membrane with a molecular weight cut off of 1000 Dalton or less (or demonstrated to reject at least 80% of the influent TOC concentration under typical operating conditions).

EPA is also proposing that, as part of the sanitary survey process, systems be required to consult with their State regarding peak excursions in TTHM and HAA5 levels that have occurred (for this provision, a peak is defined as any individual sample level exceeding 100 Fg/L for TTHM and 75 Fg/L for HAA5). Today, EPA is proposing a different BAT for consecutive systems than for wholesale systems to meet the TTHM and HAA5 LRAA MCLs (0.080 mg/L and 0.060 mg/L respectively). Consecutive systems are unique in that their source water has already been disinfected and contains DBPs that are not appropriately controlled for by the BATs proposed for wholesale systems. In lieu of the BAT proposed for wholesale systems, EPA is proposing the BAT for consecutive systems as chloramination with management of hydraulic flow and storage to minimize residence time in the distribution system. EPA is proposing that this BAT be implemented by the system: (1) maintaining a chloramine residual throughout the distribution system, (2) submitting a management plan that indicates the actions to be taken to minimize the residence time of water within the distribution system, (3) approval of the management plan by the Primacy Agency, and (4) ongoing implementation of the action plan as approved by the Primacy Agency. Minimum components of the management plan include periodic scheduled flushing of all dead end pipes and storage vessels through which water is delivered to customers, and hydraulic flow control procedures that routinely circulate water in all storage vessels within the distribution system.

2. How was this proposal developed?

a. Consideration of regulatory alternatives

As discussed previously, the Stage 2 M-DBP Advisory Committee negotiated recommendations for certain components of this Stage 2 DBPR proposal, including the TTHM and HAA5 MCLs. The members of the Advisory Committee, representing EPA, State and local governments, water utilities, equipment manufacturers, consumer advocacy groups and public health and environmental organizations, considered an array of alternative MCL strategies for TTHM, HAA5, and bromate.

During these initial discussions, the Committee primarily focused on the relative magnitude of expected benefits versus the expected impact on the water industry and its customers. The expected impact on industry was estimated by comparing various Stage 2 DBP MCL alternatives to expected reductions in DBP levels (see EA section VII) and analyzing predictions of treatment technology changes that would be required to meet these MCLs.

The expected benefits of different regulatory alternatives were much more difficult to estimate. At issue was the ultimate public health objective of the Stage 2 DBPR. The Advisory Committee consulted with a number of toxicology and epidemiology experts regarding the weight of evidence for reproductive and developmental health effects associated with DBPs. After reviewing the science, all Committee members expressed concern for potential health risks to pregnant women and their fetuses from DBPs and all Committee members recognized that some degree of uncertainty was associated with the available health effects data. However, different perspectives on the risk remained. Some Committee members believed strongly that the epidemiological and toxicological evidence for reproductive and developmental health risks,

although uncertain, warranted immediate and stringent DBP control. These Committee members favored regulatory alternatives such as DBP levels significantly lower than the Stage 1 DBPR MCLs or MCLs based on single measurements (i.e., no averaging of DBP levels). Other Committee members believed that due to the uncertainties in the health effects data, only modest, if any, DBP control measures should be taken. These Committee members favored regulatory alternatives such as MCLs based on an LRAA instead of an RAA.

After initial discussions, the Committee primarily focused on four types of alternative rule scenarios which are illustrated below as Alternatives 1-4:

Alternative 1. MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as LRAAs. Bromate MCL of 0.010 mg/L.

Alternative 2. MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as LRAAs. Bromate MCL of 0.005 mg/L.

Alternative 3. MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as absolute maximums (i.e., no single sample could exceed the MCL). Bromate MCL of 0.010 mg/L.

Alternative 4. MCLs of 0.040 mg/L TTHM and 0.030 mg/L HAA5 as RAAs. Bromate MCL of 0.010 mg/L.

The Advisory Committee, with assistance from the TWG, conducted an in depth analysis of these types of regulatory alternatives. In the process of narrowing down alternatives, the Committee reviewed vast quantities of data that included health effects, current DBP occurrence, predicted DBP occurrence reductions that would result from each rule alternative, predicted technology changes that would be required to meet each rule alternative, and associated capital,

annual, and household costs. Details of the compliance, occurrence and cost forecasts are described in the Stage 2 DBPR Economic Analysis (EA) (USEPA, 2001d) and the Stage 2 DBPR Occurrence Document (USEPA, 2001b).

The only difference between Alternative 1 and Alternative 2 is the bromate MCL. The Committee's recommendation to maintain the Stage 1 DBPR bromate MCL of 0.01 mg/L is discussed in Section V.D. of today's proposal.

Alternatives 3 and 4 are significantly more stringent than the Stage 1 DBPR. Alternative 3 would require that all samples be below the MCL. Since DBP occurrence is variable across the distribution system and over time, water utilities would have to base their disinfectant and treatment strategies on a worst case DBP formation scenario. Alternative 4 would require a 50% reduction in the Stage 1 DBPR MCLs. This would cause a significant shift in the national distribution of treatment. Thus, the costs for Alternatives 3 and 4 are approximately an order of magnitude above the costs for Alternative 1 (see Section VII.B.).

As expected, the predicted DBP reductions for Alternatives 3 and 4, which are related to the benefits, are far greater than the DBP reduction predicted to be achieved with Alternative 1. Although all members of the Advisory Committee believed the science showing reproductive and developmental health effects associated with DBPs was sufficient to cause concern and warrant some regulatory action, they ultimately concluded that the association was not certain enough to justify a major and costly national shift in treatment technologies. Thus, the Committee rejected Alternatives 3 and 4.

In the end, the Committee recommended Alternative 1 in combination with the IDSE. Because the Committee was concerned about reproductive and developmental risks, which are

acute risks, they sought to obtain agreement on a scenario that reduced exposure from high levels of DBPs. Occurrence data showed that a significant number of high DBP levels occur even when systems are in compliance with an RAA (see section VII). In addition, data indicated that a shift to an LRAA would reduce these peaks (see section V.C.2.c. and section VII.A.). Although the LRAA was designed to reduce peak DBP occurrence, the Committee recognized it would not eliminate all DBP peaks because utilities would still be able to average sample data over an annual period. The Committee was not satisfied that simply changing the compliance calculation from an RAA to an LRAA would produce sufficient decreases in DBP peak levels. This led the Committee to recommend that compliance monitoring sites be reevaluated to ensure that they were located at points in the distribution systems with the highest TTHM and HAA5 levels (see section V.E.2.a. for a discussion of the IDSE requirement). In conclusion, the Committee decided that Alternative 1 in combination with the IDSE, which is predicted to achieve moderate reductions in DBPs on average and target points within the distribution system with peak DBP levels at a reasonably low cost, was the preferred rule scenario.

EPA believes that the recommendation of Alternative 1 is logical. The science demonstrating both cancer and reproductive/developmental health effects associated with DBPs, in conjunction with occurrence data that shows that a significant number of high DBP levels occur under current regulatory scenarios, justify a change in regulation. However, EPA recognizes the remaining uncertainties regarding the available health effects data. The actual reproductive and developmental risk from DBPs cannot be quantified. EPA thus believes that the LRAA alternative in combination with the IDSE is a judicious selection. This proposal achieves an appropriate balance between the available science and the uncertainties. Although it

will not remove all DBP occurrence peaks, this proposed regulation will ensure that DBP exposures across a utility's distribution system are more equitable and will achieve cancer and reproductive and developmental risk reduction benefits.

b. Definition of an LRAA

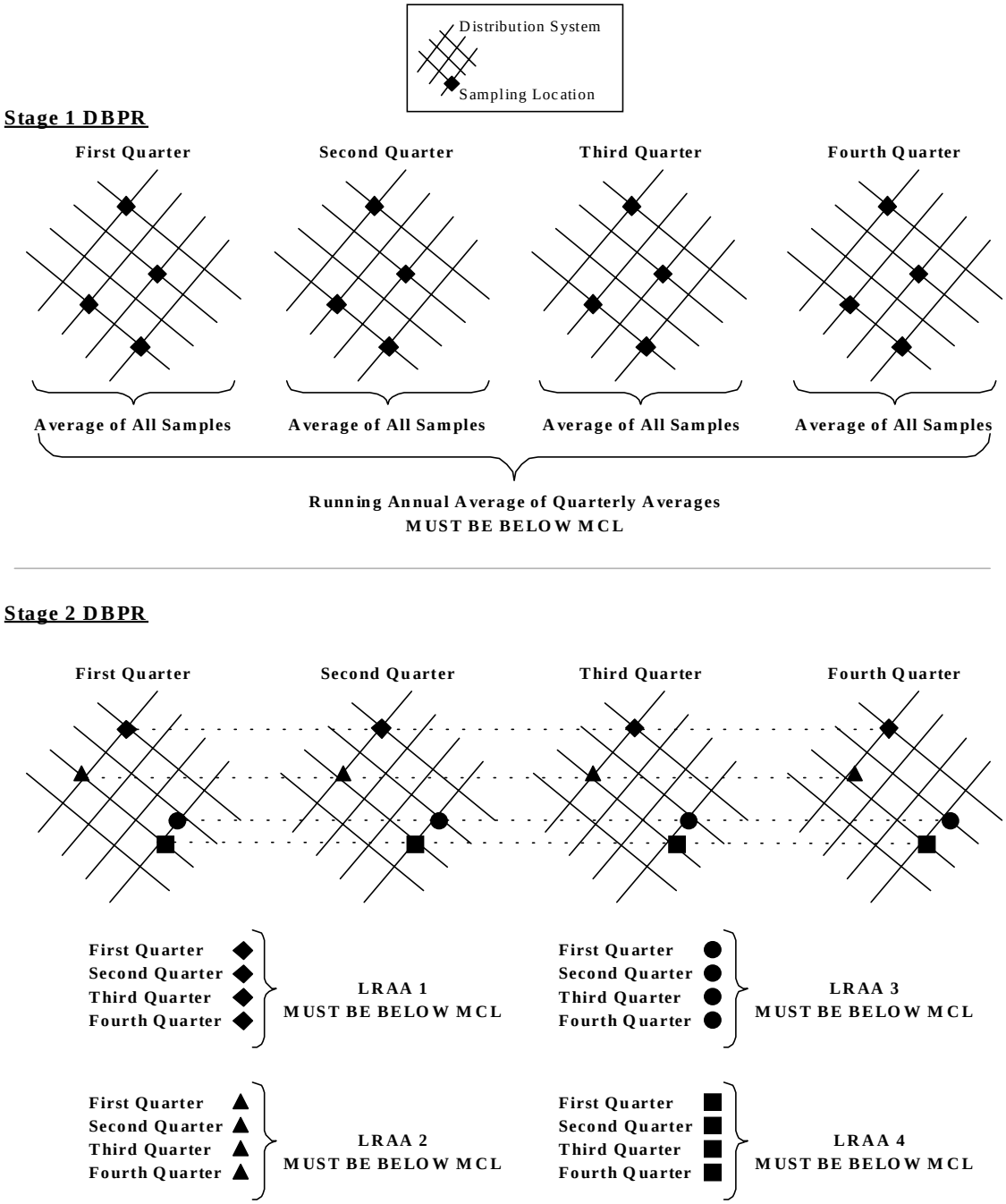
The primary objective of the LRAA is to reduce exposure to high DBP levels. The compliance basis of the 1979 TTHM rule and the Stage 1 DBPR is a system-wide annual average (referred to as a running annual average, or RAA) under which, the effect of high DBPs in one location can be dampened by averaging across the distribution system. Systems with multiple plants can average results from plants with varying source water quality and type (i.e., plants with a higher quality source water and lower DBP results can offset plants with higher DBP levels). For an LRAA, an annual average must be computed at each monitoring site. The incremental reduction in exposure expected between the Stage 1 and Stage 2 DBPRs is a result of these two different compliance calculation methodologies. This section will discuss and illustrate the difference in how the RAA and LRAA are calculated. Section VII (Economic Analysis) quantifies the expected impact of the Stage 2 DBPR LRAAs on byproduct levels in distribution systems.

The ICR data shows that a system in compliance with a RAA MCL could have TTHM or HAA5 occurrences well above the MCL (see section V.C.2.c.). Under today's proposed Stage 2 DBPR, systems will be required to meet MCLs as an annual average at each individual sampling location rather than across the distribution system as a whole. Each sampling point should have a running annual average that does not exceed 0.120 mg/L TTHM and 0.100 mg/L HAA5 during Stage 2 A of the rule and thereafter 0.080 mg/L (80 Fg/L) TTHM and 0.060 mg/L (60 Fg/L)

HAA5 (i.e., compliance with the MCLs will be based on an LRAA). Therefore, systems will need to take steps to specifically address high occurrence points, because they will no longer be dampened by a spatial average.

Figure V.1 illustrates the difference in calculating compliance with the MCLs for TTHM between a Stage 1 DBPR RAA, and the proposed Stage 2 DBPR LRAA.

Figure V.1. Comparison of RAA and LRAA compliance calculations[1].



[1] Stage 2 DBPR sampling locations will be selected based on the results of an IDSE study and may occur at different locations than Stage 1 DBPR sampling sites.

c. Basis for the LRAA

There is considerable evidence that under an RAA a significant proportion of high DBP levels occur. Surface water and ground water systems (serving ≥ 10,000) are regulated by the 1979 TTHM rule which set a TTHM MCL of 0.100 mg/L as an RAA. Under the Stage 1 DBPR, which also uses a RAA, ground water systems serving > 10,000 will not be required to comply with the new MCLs until December 2002 and surface water systems < 10,000 and all ground water systems will not be required to comply until December 2004. As summarized in section IV of the preamble, ICR surface water and ground water systems (large systems serving ≥ 100,000), had some TTHM levels that ranged up to 300 μg/L (Table IV.5). Surface water systems had some HAA5 levels over 200 μg/L, while ground water systems had HAA5 levels over 100 mg/L (Table IV.5). In addition, many members of the TWG were concerned that the ICR did not truly capture the highest DBPs in the distribution system due to the ICR method of sample site selection. If this concern is valid, then even higher DBP levels than were reported in the ICR are likely to be found in distribution systems operating under an RAA based regulation.

Peak values in the ICR data are consistently much higher than corresponding averages of the distribution system samples. In fact, the highest TTHM and HAA5 levels of the four distribution system samples taken each quarter are about 20% higher than the average of the the four samples (Table IV.5). A paired analysis of the average level and the corresponding highest level is shown in Figures V.2 and V.3 for TTHM and HAA5, respectively. The figures show that highest plant values (DS Highest) in the ICR data are consistently higher than corresponding per quarter plant averages (DS Average) of the distribution system samples. In some cases, highest values are not much higher than the average, while in other cases, there is a greater

magnitude of difference and hence averaging has a greater dampening effect. Three main points can be deduced from these plots:

- There is inequity in the distribution system as evidenced by the variability between the average value and the highest value (i.e., the difference ranges from 0 to 204 µg/L).
- For the distribution system averages that are under 80/60 µg/L (the Stage 1 MCLs), some distribution system highest values are greater than 80/60, particularly as the average approaches the compliance level.
- When the distribution system average value is > 80/60 µg/L, some of the distribution system highest levels are more than double the MCL.

Figure V.2. Comparison of paired TTHM DS Average and DS Highest concentrations.

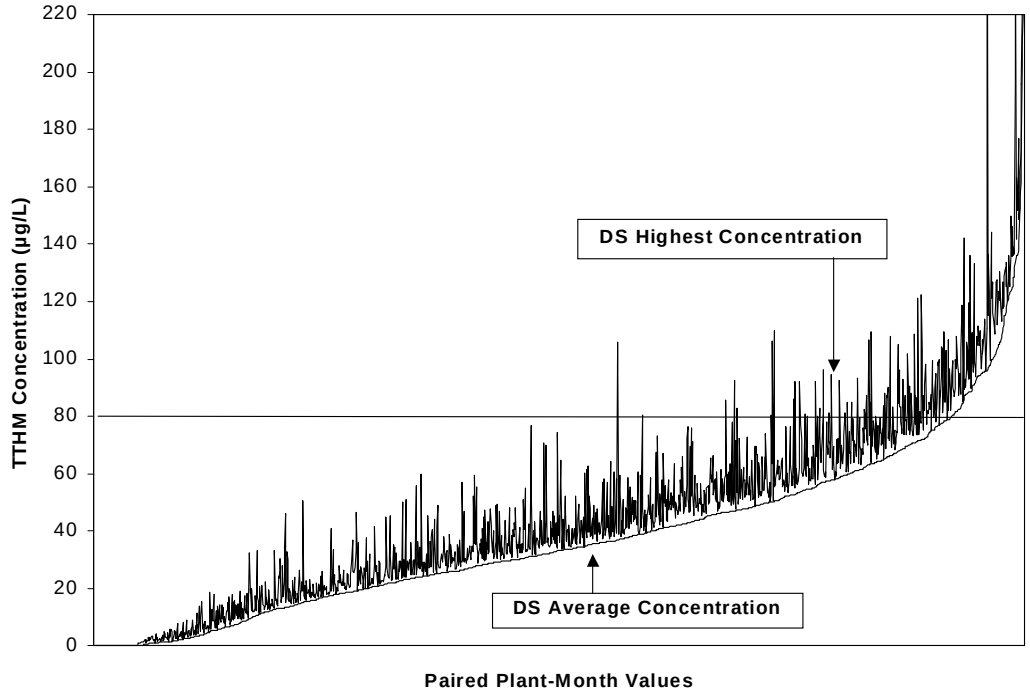
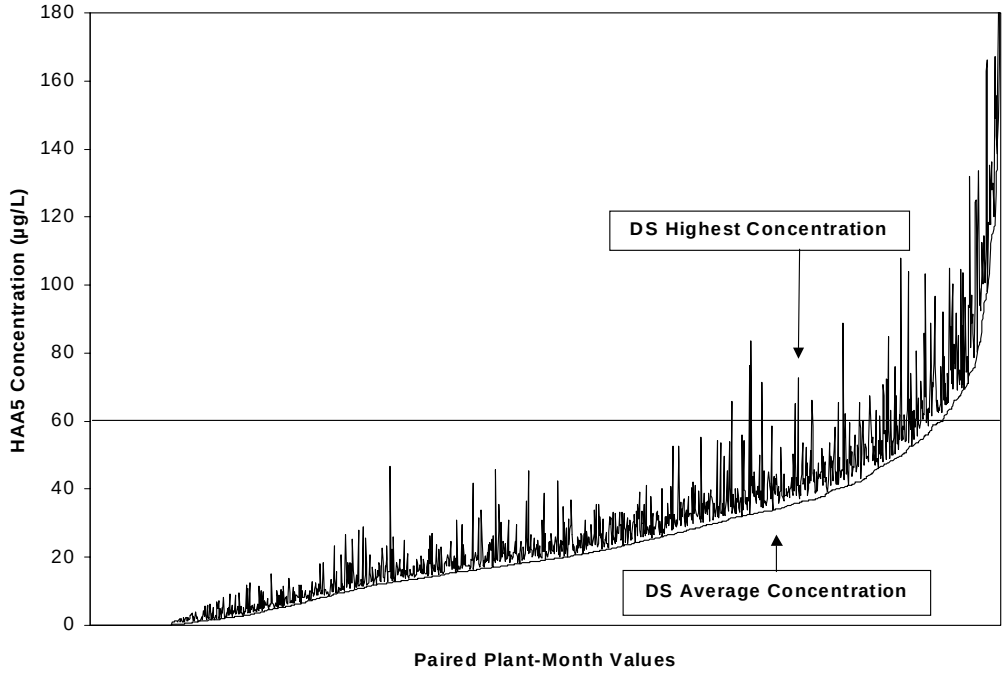
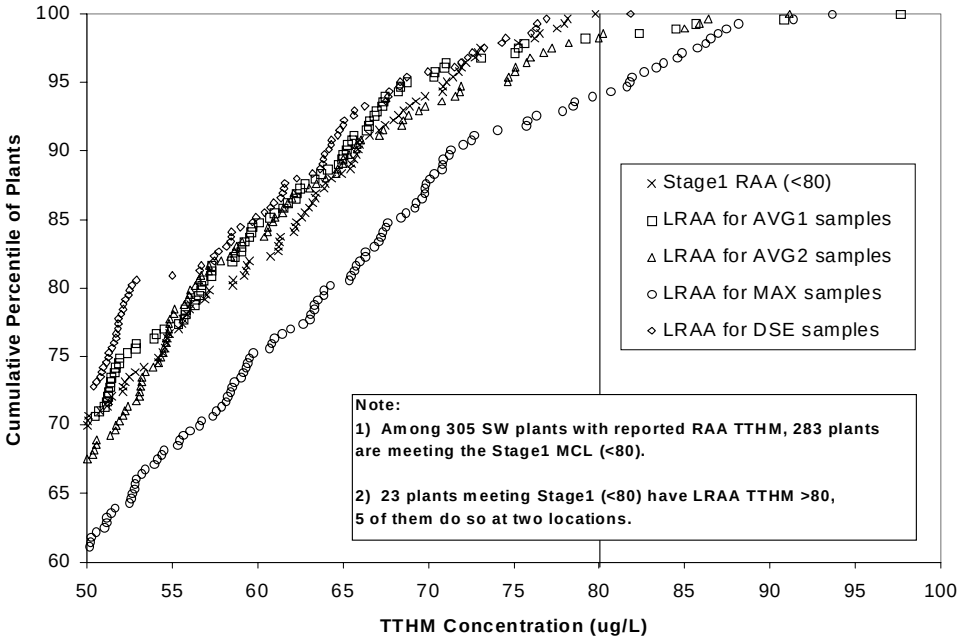


Figure V.3. Comparison of paired HAA5 DS Average and DS Highest concentrations.



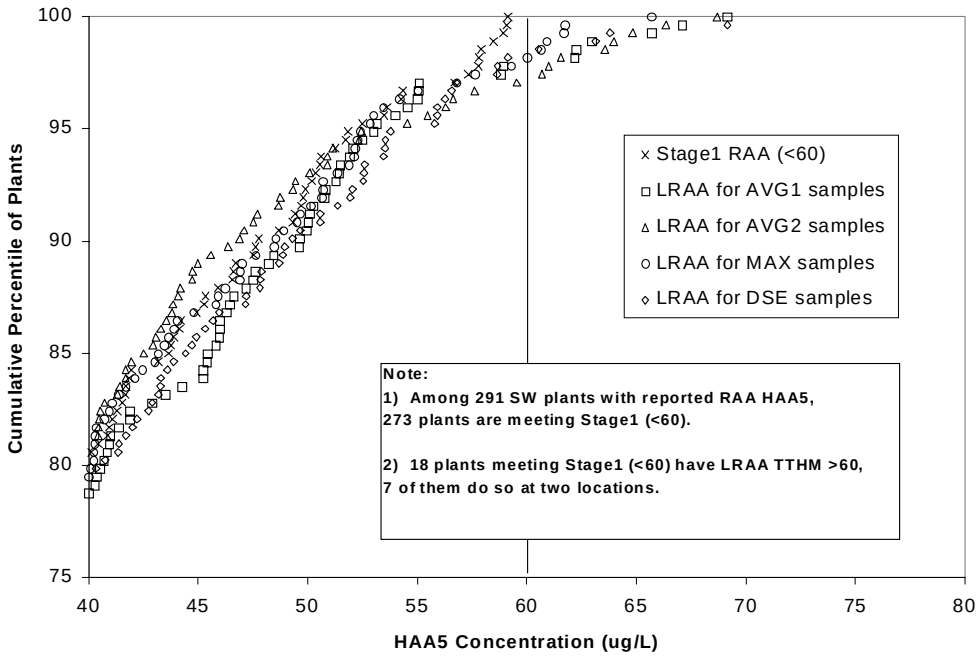
An RAA allows some locations within a distribution system, to have higher DBPs than others, because of the expected dampening effect of spatial averaging discussed previously. In some situations, the population served by certain portions of the distribution system may receive water that exceeds the MCL even though the system is in compliance. As shown in Figure V.4, which compares RAA and LRAA calculations for the ICR surface water plants (months 7 to 18 of the monitoring), an RAA calculation does not represent the variability in exposure at sampling locations across the distribution system. This is particularly of concern for distribution system points where the DBP concentrations are highest, shown here most frequently as the MAX sampling location. Figure V.4 shows that, based on ICR data, eight percent of plants that could achieve compliance with the Stage 1 TTHM MCL (80 Fg/L based on an RAA) would have a particular sampling location that, on average, exceeded 80 Fg/L for that same year. Five out of 23 plants that exceeded the 80 µg/L did so at two locations. Customers served at those points will receive water with TTHMs higher than the MCL. Figure V.5 shows similar results based on ICR HAA5 data, with six percent of plants that could meet the Stage 1 MCL (60 Fg/L as an RAA) exceeding 60 Fg/L based on an LRAA, and 7 of these 18 plants doing so at two locations.

Figure V.4. Comparison of TTHM RAA and LRAAs for Surface Water plants[1,2]



[1] The data shown are for surface water plants that would not exceed 0.080 mg/L as an RAA when calculated using the last 4 quarters of ICR data.
[2] ICR plants collected 4 distribution system samples each quarter: 2 at average residence time locations (AVG1 and AVG2); a maximum residence time location sample (MAX); and a distribution system equivalent (DSE) sample.

Figure V.5. Comparison of HAA5 RAA and LRAAs for Surface Water Plants[1,2].



[1] The data shown are for surface water plants that would not exceed 0.060 mg/L as an RAA when calculated using the last 4 quarters of ICR data.
[2] ICR plants collected 4 distribution system samples each quarter: 2 at average residence time locations (AVG1 and AVG2); a maximum residence time location sample (MAX); and a distribution system equivalent (DSE) sample.

The 1979 TTHM rule and the Stage 1 DBPR both allow systems to average all of the samples taken across the distribution system. Equal weight is given to all samples. Compliance based on an LRAA will remove the opportunity for systems to give equal weight to samples from high and low quality water sources. Some systems are able to comply with a RAA even if they have a plant that produces high DBPs because they have at least one sample point associated with another plant that has a higher quality water source. Even though the population served by the plant with high DBPs has higher DBP exposure than the population served by the other plant, the system is still in compliance with the RAA standard because samples from the plant with the high quality water source lower the distribution system average DBP level. An LRAA standard will eliminate system wide averaging thus ensuring that average DBP exposures at different locations in the distribution system are all below the same level.

In summary, EPA has chosen compliance based on an LRAA due to concerns about high levels of DBPs in the distribution system. The populations served by areas with peak occurrence levels masked by averaging are not receiving an equitable or adequate level of health protection. Although an LRAA standard still allows averaging over an annual period, EPA believes that changing the basis of compliance from an RAA to an LRAA will result in decreased exposure to high DBP levels (see section VII.A. for predictions of DBP reductions under the LRAA MCLs).

d. Stage 2 A MCLs for TTHM and HAA5

The Advisory Committee strongly recommended that EPA maintain the principle of simultaneous compliance for DBP and microbial rules that was advocated by the 1992 regulatory negotiating committee, affirmed by the SDWA 1996 Amendments, and incorporated in the Stage

1 M-DBP rules (USEPA, 1998 c&d). EPA believes that simultaneous compliance is necessary for systems to maintain microbial protection while reducing DBP exposure.

Today, EPA is proposing phased MCLs for TTHM and HAA5, as recommended by the Stage 2 M-DBP Advisory Committee, in order to maintain parallel rule compliance schedules for the Stage 2 DBPR and the LT2ESWTR and comply with statutory requirements for risk balancing (Section 1412(b)(5)).

All surface water systems will have to complete source water microbial assessments in order to know their *Cryptosporidium* control requirements under the LT2ESWTR. EPA has developed a phased schedule for all systems complying with the Stage 2 DBPR to enable surface water systems to make decisions about treatment strategies appropriate to achieve compliance with both the LT2ESWTR and the Stage 2 DBPR. For Stage 2 A, EPA is proposing that all systems continue to comply with Stage 1 DBPR MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as an RAA and comply with transition MCLs of 0.120 mg/L TTHM and 0.100 mg/L HAA5 as an LRAA (based on the same sample locations as under Stage 1 DBPR), until systems are aware of their site-specific microbial prevention criteria. The Advisory Committee recommended these specific transition MCLs to incrementally move systems to compliance with location-specific MCLs and conserve simultaneous compliance. See section V.F. and §141.10xx for proposed monitoring provisions and section V.G. and §141.10xx of the rule for further discussion of the proposed compliance schedules.

Stage 2 A of this proposed rule does not require systems to conduct any new monitoring. They will continue to monitor at Stage 1 DBPR locations. For this reason, Stage 2 A only applies to systems that monitor at more than one site. Generally, this requirement will only

affect medium and large surface water systems (serving at least 10,000 people) or systems with multiple plants. The majority of ground water systems and small surface water systems will meet Stage 2 A requirements under the Stage 1 DBPR.

e. Stage 2 B MCLs for TTHM and HAA5

In Stage 2 B, systems must comply with long-term MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as LRAAs based on new sampling sites identified under the IDSE. Under the phased rule strategy, surface water systems will begin complying with Stage 2 B of this rule at the same time as they begin to comply with LT2ESWTR requirements (USEPA, 2002). See section V.F. and §141.10xx for proposed monitoring provisions and section V.G. and §141.10xx of the rule for proposed compliance schedules.

In the Stage 1 DBPR, EPA determined that both TTHM and HAAs should be regulated because they represent chlorination byproducts that occur at high levels, and are produced from a range of waters. From the HAA class, EPA decided to regulate five HAAs (HAA5) because at the time of the Stage 1 DBPR proposal, reliable methods and occurrence data were not available for the other four HAAs. The combination of TTHM and HAA5 exemplifies a variety of degrees of bromination and serves as a surrogate for unidentified and unregulated DBPs.

Although methods now exist for all nine HAAs, the Advisory Committee recommended that EPA maintain an MCL for HAA5. Continuity with the Stage 1 DBPR was maintained to the extent possible to ease the transition to the Stage 2 DBPR, especially for small systems. The objective of the Stage 2 DBPR is to shift the MCL compliance calculation to target DBP peaks in the distribution system. EPA does not believe that revising the MCL to encompass HAA6 or

HAA9 would significantly further this objective. EPA believes that controlling the occurrence levels of TTHM and HAA5 will control the levels of all of the HAAs to some extent.

Another factor in the determination to maintain HAA5 as the regulated entity is that EPA does not have new information on the health effects of BCAA, BDCAA, DBCAA, or TBAA that indicates a specific risk from these HAAs. EPA has an extensive research program underway that includes studies on these HAAs. If, in the future, research indicates that a risk from any one of these species is significantly greater than that of the individual TTHM or HAA5 species and that controlling for these HAAs would result in greater protection, EPA will consider revising the HAA regulatory strategy.

f. Basis for the BAT

The Safe Drinking Water Act directs EPA to set the MCL as close to the MCLG as is technically and economically feasible to achieve and to specify in the rule such best available technology (BAT). Systems unable to meet the MCL after application of BAT can get a variance (see section V.I. for a discussion of variances). Systems that obtain a variance must meet a schedule approved by the State for coming into compliance. Systems are not required to use BAT in order to comply with the MCL. They can use other technologies as long as they meet all drinking water standards and are approved by the State.

Today, EPA is proposing the BAT for the TTHM and HAA5 LRAA MCLs (0.080 mg/L and 0.060 mg/L respectively) as one of the three following technologies with chlorine as the primary and residual disinfectant:

- GAC adsorbers with at least 10 minutes of empty bed contact time and an annual average reactivation/replacement frequency no greater than 120 days.

- GAC adsorbers with at least 20 minutes of empty bed contact time and an annual average reactivation/replacement frequency no greater than 240 days.
- Nanofiltration using a membrane with a molecular weight cut off of 1000 Dalton or less (or demonstrated to reject at least 80% of the influent TOC concentration under typical operating conditions).

EPA examined alternatives for BAT using two different methods. In the first, EPA analyzed data from the ICR treatment studies. The treatment studies were designed to evaluate the technical feasibility of using GAC and nanofiltration (NF) to remove DBP precursors prior to the addition of chlorine based disinfectants. Applicability to the ICR treatment study requirement was based on TOC levels in the source or finished water. Specifically, surface water plants with annual average source water TOC concentrations greater than 4 mg/L and ground water plants with annual average finished water TOC concentrations greater than 2 mg/L were required to conduct treatment studies. Thus, the plants required to conduct treatment studies generally had waters with organic DBP precursor levels that were significantly higher than the national medians of 2.1 mg/L and 0.7 mg/L for ICR surface and ground water plants, respectively (USEPA, 2001b).

Plants that conducted GAC typically evaluated performance at two empty bed contact times, 10 and 20 minutes, and over a range of operational times to evaluate the un-steady state nature of TOC removal by GAC. This allowed GAC performance to be assessed with respect to empty bed contact time as well as reactivation/replacement frequency. Plants which conducted membrane treatment studies evaluated one or two nanofiltration membranes with molecular weight cut offs less than 1000 Daltons. Regardless of the technology evaluated, all treatment

studies evaluated DBP formation in the effluent from the advanced process under distribution system conditions representative of the full-scale plant at the average residence time and using free chlorine as the primary and residual disinfectant. For more information on the ICR treatment study requirement and testing protocols, see USEPA 1996 a&b.

Based on the ICR treatment study results, GAC would be an appropriate technology for surface water systems and some ground water systems, with influent TOC concentrations below approximately 6 mg/L (based on the ICR and NRWA data, over 90% of plants have average influent TOC levels below 6 mg/L (USEPA, 2001b). Larger utilities would likely realize an economic benefit from on-site reactivation, which could allow them to use smaller, 10-minute empty bed contact time contactors with more frequent reactivation (i.e., 120 days or less). Most small utilities would not find it economically advantageous to install on-site carbon reactivation facilities, and thus would opt for larger, 20-minute empty bed contact time contactors, with less frequent carbon replacement (i.e., 240 days or less). EPA recognizes that some small systems attempting to implement GAC20 may face GAC supply challenges.

Theoretically, there is a linear relationship between empty bed contact time and reactivation interval. Assuming equivalent performance, a doubling of the empty bed contact time is posited to result in a doubling of the reactivation interval. If this is the case, the 10-minute empty bed contact time contactor reactivated at 120 days should result in equivalent performance to a 20-minute empty bed contact time contactor reactivated at 240 days. However, the ICR treatment study data demonstrated that the 20-minute contactors generally outperform the 10-minute contactors on a normalized basis. On the other hand, larger systems will typically operate with a larger number of parallel contactors compared to small systems, resulting in

improved performance. Thus, the benefit that small systems gain by using a larger empty bed contact time will be offset by use of a smaller number of parallel contactors. Based on these considerations, the proposed reactivation/replacement interval for the 20 minute contactor is simply double the reactivation/replacement interval for 10 minute contactor.

The ICR treatment study data demonstrated that approximately 70% of the surface water plants that conducted GAC studies could meet the 80/60 TTHM/HAA5 MCLs with a 20% safety factor using GAC with 10 minutes of empty bed contact time and a 120 day reactivation frequency, and 78% of the plants could meet the MCLs using GAC with 20 minutes of empty bed contact time and a 240 day reactivation frequency. As discussed previously, the treatment studies were conducted at plants with poorer water quality than the national average. Therefore, EPA believes that the percentages of plants that conducted the GAC studies that could meet the MCLs with the proposed BATs translate to much higher percentages of plants nationwide.

The ICR treatment study results also demonstrated that GAC was not an effective DBP control technology for groundwater sources with high TOC concentrations (i.e., above approximately 6 mg/L). However, the results of the membrane treatment studies showed that all ground water plants could meet the 80/60 TTHM/HAA5 MCLs with a 20% safety factor at the average distribution system residence time using nanofiltration. Although nanofiltration is generally more expensive than GAC, it would be less expensive than GAC for high TOC ground waters that require minimal pretreatment. Also, nanofiltration is accepted technology for treatment of high TOC ground waters in Florida and parts of the southwest, areas of the country with elevated TOC levels in ground waters.

The second method that EPA used to examine alternatives for BAT was the SWAT model that was developed to compare alternative regulatory strategies. EPA considered the following BAT options: enhanced coagulation/softening with chlorine; enhanced coagulation/softening with chlorine and no predisinfection; enhanced coagulation and GAC10; enhanced coaglation and GAC 20; enhanced coagulation and chloramines. Enhanced coagulation/softening is required under the Stage 1 DBPR for conventional plants. In the model GAC 10 was defined as granular activated carbon with an empty bed contact time of 10 minutes and a reactivation frequency of no more than 90 days. GAC 20 was defined as granular activated carbon with an empty bed contact time of 20 minutes and a reactivation or replacement frequency of no more than 90 days. EPA assumed that systems would be operating to achieve both the Stage 2 B MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as an LRAA and the SWTR removal and inactivation requirements of 3-log for *Giardia* and 4-log for viruses. EPA also evaluated the BAT options under the assumption that plants operate to achieve DBP levels 20% below the MCL (safety factor). These assumptions along with other inputs for the SWAT runs are consistent with those used in the Economic Analysis document of today's proposed rule (USEPA, 2001d).

The compliance percentages forecasted by the SWAT model are indicated in Table V.1. EPA estimates that over 97% of large systems will be able to achieve the Stage 2 B MCLs regardless of post-disinfection choice if they were to apply the proposed BAT (McGuire Memo, 2001). Based on the large system estimate, EPA believes it is conservative to assume that at least 90% of medium and small systems will be able to achieve the Stage 2 B MCLs if they were to apply the proposed BAT.

Table V.1. SWAT model predictions of percent of large plants in compliance with TTHM and HAA5 Stage 2 B MCLs after application of specified treatment technologies.

Technology	Compliance with 80/60 LRAA			Compliance with 64/48 LRAA (20% Safety Factor)		
	Residual Disinfectant		***All Systems***	*Residual Disinfectant*		***All Systems***
	Chlorine	***Chloramine***		***Chlorine***	***Chloramine***	
Enhanced Coagulation (EC)	73.5%	76.9%	74.8%	57.2%	65.4%	60.4%
EC (no predisinfection)	73.4%	88.0%	78.4%	44.1%	62.7%	50.5%
EC & GAC10	100%	97.1%	99.1%	100%	95.7%	98.6%
EC & GAC20	100%	100%	100%	100%	100%	100%
EC & All Chloramines	NA	83.9%	NA	NA	73.6%	NA

Today, EPA is also proposing a BAT for consecutive systems to meet the TTHM and HAA5 MCLs of 0.080 and 0.060 mg/L respectively. Presumeably, consecutive systems that may need to employ the BAT are receiving water from their wholesaler(s) that just barely or does not meet the MCLs. Removal of TTHM and HAA5 after they have been formed is difficult. EPA believes that the best compliance strategy for consecutive systems is to specify water quality in their contractual agreements with their wholsaler(s). However, this is a private agreement over which EPA does not have jurisdiction. Thus, for the contingency that the consecutive systems cannot work out agreements with the wholesaler for treating the water to enable the consecutive system to meet the MCLs, EPA is proposing the BAT for consecutive systems as chloramination with management of hydraulic flow and storage to minimize residence time in the distribution system. The associated BAT provision to manage hydraulic flow and minimize residence time in the distribution system is to facilitate the maintenance of the chloramine residual and minimize the likelihood for nitrification. If consecutive systems receive chlorinated water that is close to but lower than the MCLs, they should in most cases be able to use chloramination to stop the formation of THMs and HAAs in their distribution system and thereby meet the MCL. If consecutive systems are already receiving chloraminated water from the wholesaler that is meeting the MCLs, the consecutive system should also be able to meet the MCL. In either of these situations distribution system flow maintenance is important for maintaining the chloramine residual.

EPA believes that the various BATs proposed for wholesale systems are not appropriate for consecutive systems because each of these BATs when applied to water with high levels of DBPs raises other concerns. EPA believes GAC is not a good BAT for consecutive systems

because GAC is not cost effective for removing DBPs and dioxin, a potent carcinogen, that is a byproduct of GAC regeneration when GAC has been used to adsorb chlorinated DBPs. While nanofiltraton is effective for removing TOC, it is generally not effective for removing THMs or HAAs. Nanofiltration can be moderately effective at removing THMs or HAAs but only with membranes that have a very low molecular weight cutoff and very high cost of operation. Therefore, EPA believes that nanofiltraton is not a good BAT for consecutive systems.

g. Peak TTHM and HAA5 levels

Since systems are allowed to average their compliance measurements over a one year period, even when a system is in compliance with an MCL as an LRAA, there will likely be occurrence levels that exceed the MCL. The Advisory Committee was concerned about these peak exposures and the possible risk they might pose. Thus, the Committee recommended that these peak occurrences be monitored in Stage 2 B. They recommended that, as part of the sanitary survey process, systems be required to consult with their State regarding peaks in TTHM and HAA5 levels that have occurred. The State may recommend measures to reduce peaks based on EPA guidance. For this provision, EPA proposes the following definition of a peak: any sample level greater than or equal to 0.100 mg/L TTHM or 0.075 mg/L HAA5 (25% over the respective MCLs). The definition of a peak as 25% greater than the MCL was based on an analysis of the ICR data. From this analysis, EPA estimates that approximately 10% of plants that achieve compliance with the Stage 2 B MCLs may need to consult with their State due to peak excursions. EPA believes that an impact to 10% of plants is reasonable and not overly burdensome.

EPA will prepare guidance for systems and States on how to conduct peak excursion evaluations and how to reduce peaks.

3. Request for comment

EPA requests comment on the alternative MCL strategies that were considered by the negotiating committee and the determination to propose Alternative 1 in combination with the IDSE as the preferred regulatory strategy. EPA also requests comment on whether the proposed approach will reduce peak DBP levels.

EPA requests comment on the phased MCL strategy and whether or not Stage 2 A is necessary to maintain simultaneous compliance. EPA also requests comment on the transition MCLs of 0.120 mg/L TTHM and 0.100 mg/L HAA5 as an LRAA and on the long-term MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as an LRAA,.

EPA solicits opinions on whether HAA5 is an adequate surrogate for all the HAAs and whether it is the appropriate subset of HAAs to regulate. EPA also requests comment on the use of TTHM and HAA5 as surrogates for DBPs in general and the assumption that reducing TTHM and HAA5 reduces other identified and unknown DBPs.

EPA also requests comment on the BATs proposed for these MCLs and the BAT for consecutive systems.

EPA requests comment on the requirement for systems to consult with their State on peak excursions of DBP occurrence and on the definition of a peak. Is the sanitary survey the appropriate mechanism for reviewing peak occurrence data with the State? Should a system be required to take corrective action when DBP peak levels occur? If so, when should these take place? EPA also solicits comment on whether systems should be required to notify the State of

peak levels within a short time-frame, prior to the sanitary survey. If so, what time-frame should be specified?

D. MCL and BAT for bromate

1. What is EPA proposing today?

Due to concerns with risk trade-offs, EPA is proposing that the MCL for bromate remain at 0.010 mg/L as an RAA as established by the Stage 1 DBPR. EPA is proposing this based on the recommendation of the Stage 2 M-DBP Advisory Committee which considered the present potential that reducing the bromate MCL could both increase the concentration of other DBPs in the drinking water and interfere with the efficacy of microbial pathogen inactivation and recommended, for purposes of the Stage 2 DBPR, that the bromate MCL remain at 0.010 mg/L. In addition, as required by the SDWA and based on the advice of the Advisory Committee, EPA will review the bromate MCL as part of the 6-year review and determine whether the MCL should remain at 0.010 mg/L or be reduced to a lower concentration. As a part of that review, EPA will consider the increased utilization of alternative technologies, such as UV, and whether the risk/risk concerns reflected in today's proposal remain valid. It is a very real possibility that EPA may, in the future, lower the MCL for bromate.

Because EPA is not revising the Stage 1 DBPR bromate MCL, EPA is not proposing a revised BAT for bromate. The Stage 1 DBPR BAT for bromate is defined as control of ozone treatment process to reduce production of bromate.

2. How was this proposal developed?

Bromate is a principal byproduct from ozonation of bromide-containing source waters. As described in more detail below, lowering the bromate MCL has the potential to decrease

current levels of microbial protection, impair the ability of systems to control resistant pathogens like *Cryptosporidium,* and increase levels of DBPs from other disinfectants that may be used instead of ozone.

EPA estimates that the 1 in 10,000 excess lifetime cancer risk level for bromate is 0.005 mg/L. EPA proposed and ultimately finalized an MCL of 0.010 mg/L in the Stage 1 DBPR, primarily because available analytical detection methods for bromate could only reliably measure to 0.01 mg/L (USEPA, 1994b). Analytical methods for bromate are now available to quantify bromate concentrations as low as 0.001 mg/L. Due to the availability of lower detection methods for bromate, as part of the Stage 2 M-DBP Advisory Committee deliberations, EPA considered revising the MCL to 0.005 mg/L or lower.

As a disinfectant, ozone is highly effective against a broad range of microbial pathogens including bacteria, viruses, and protozoa. Moreover, ozone is one of the few disinfectants available in water treatment that is capable of inactivating *Cryptosporidia*, protozoa which can cause severe intestinal disorders and can be deadly to those with compromised immune systems. The oxidizing properties of ozone are also valuable for treatment objectives like control of foul tastes and odors and removal of iron and manganese. In contrast, chlorine, the most common disinfectant and oxidant in water treatment, is substantially less effective for controlling *Cryptosporidia*. Chlorine dioxide, while capable of providing low levels of inactivation for *Cryptosporidia*, typically cannot be used at high doses without violating the MCL for chlorite, a byproduct of chlorine dioxide. UV light is highly effective against *Cryptosporidia* and *Giardia* and most viruses.

As of early 2000, there were 332 plants of various system sizes using ozone (Overbeck, 2000) and 58 plants which were planning to install ozonation (Rice, 2000 - personal communication: email 7/14/2000). A significant percent of current ozone plants use ozone for some portion of their disinfection objective (Rice, 2000 - personal communication: email 7/14/2000). An ozone system that could not meet a 0.005 mg/L bromate MCL would have three primary options: decrease the ozone dose; switch to a different disinfectant; or install an advanced filtration process such as membranes, sometimes in combination with the first two options. Of these three options, the third is likely effective but very expensive, while the first two create the risk either of reducing microbial protection for a wide range of microbial pathogens, or of increasing formation of DBPs other than bromate.

In an attempt to achieve a lower level of bromate, some systems might be driven to reduce the applied ozone dose to the minimum necessary for regulatory compliance or switch to other treatment processes. Many systems currently achieve more disinfection than is required by the SWTR and if a system were to simply lower the ozone dose, protection from pathogens may be compromised. In addition, since inactivation of *Cryptosporidium* requires much higher ozone doses than *Giardia* inactivation, systems cannot achieve *Cryptosporidium* inactivation with low ozone doses.

Alternatively, if a system were to lower the ozone dose and supplement with an additional disinfectant or switch entirely to a different disinfectant, the system may not achieve the same level of microbial protection as is afforded by ozonation. Also, other potentially harmful byproducts from the new disinfectant would be produced.

During the Stage 2 M-DBP Advisory Committee discussions, the TWG evaluated the impact of reducing the bromate MCL from 0.010 mg/L to 0.005 mg/L as an annual average. The TWG concluded that many systems currently using ozone or predicted to install ozone to inactivate microbial pathogens would have significant difficulty maintaining bromate levels at or below 0.005 mg/L. In the ICR survey of systems serving greater than 100,000 people, all of the ozone plants had annual average bromate concentrations below the 0.010 mg/L level (USEPA, 2001b). However, approximately 20% of the ICR ozone plants did not meet the 0.005 mg/L level. Under the assumption that utilities operate their plants using a safety margin of 20% below the MCL, approximately 30% of ICR ozone plants did not reliably attain this level. During the ICR, for the first half of 1998, much the U.S. was wetter than normal (http://www.cpc.noaa.gov/products/monitoring_and_data/drought.html). This hydrogeological condition often leads to lower than normal bromide levels. In the second half of 1998, California continued to experience El Nino rains (40% of ICR ozone plants were located in California) but many other areas of the country such as Texas and Florida experienced a drought. The percentage of ozone systems unable to achieve 0.005 mg/L bromate would likely increase during years in which bromide levels in California were elevated as consequence of drought.

The ability of systems to use ozone to meet *Cryptosporidia* treatment requirements proposed under the LT2ESWTR would be diminished if the bromate MCL was decreased from 0.010 to 0.005 mg/L. The proposed LT2ESWTR will require a subset of systems, based on source water pathogen levels, to provide from 1.0 to 2.5 logs of additional treatment for *Cryptosporidia*. Ozone doses required to inactivate *Cryptosporidia* are substantially greater than those required for *Giardia* and viruses. To assess the potential impact of a lower bromate MCL

on the ability of systems to treat for *Cryptosporidia*, the TWG estimated the percentage of treatment plants that could use ozone to inactivate from 0.5 to 2.5 log of *Cryptosporidia* without exceeding a bromate MCL of either 0.005 or 0.010 mg/L (cite TWG graphs). These estimations were based on analyses of ICR source water quality data, coupled with projected ozone dose requirements for *Cryptosporidia*. This analysis suggests that 88% of systems could use ozone to achieve 1 log of *Cryptosporidia* inactivation and 47% could inactivate 2 log while complying with a bromate MCL of 0.010 mg/L. With the bromate MCL reduced to 0.005 mg/L, though, these estimates drop to 67% of systems able to inactivate 1 log of *Crytptosporidia* with ozone and only 14% able to inactivate 2 log. The number of plants predicted to be able to treat for *Cryptosporidia* with ozone and meet a 0.005 mg/L standard was further reduced when periods of higher bromide levels, similar to drought conditions, were modeled. Thus, as systems are required to meet more stringent inactivation requirements, a large number of systems would be forced to select treatment processes other than ozone if the bromate standard were lowered to 0.005 mg/L.

The 1996 Safe Drinking Water Act Amendments, section 1412(b)(5)(A), specifically provide for risk-risk trade-off situations in which the regulation of one contaminant may result in or lead to higher health risk from increased exposure to another harmful parameter. The Amendments state that "the Administrator may establish a maximum contaminant level for a contaminant at a level other than the feasible level, if the technology, treatment techniques, and other means used to determine the feasible level would result in an increase in the health risk from drinking water by (i) increasing the concentration of other contaminants in the drinking

water; or (ii) interfering with the efficacy of drinking water treatment techniques or processes that are used to comply with other national primary drinking water regulations."

The Stage 2 M-DBP Advisory Committee considered the present potential that reducing the bromate MCL to 0.005 mg/L could both increase the concentration of other DBPs in the drinking water and interfere with the efficacy of microbial pathogen inactivation. Therefore, the Committee recommended, for purposes of the Stage 2 DBPR, that the bromate MCL remain at 0.010 mg/L. The Advisory Committee also recommended that EPA review the bromate MCL as part of the 6-year review and determine whether the MCL should remain at 0.010 mg/L or be reduced to a lower concentration.

Today, EPA is proposing the Advisory Committee's recommendation to leave the bromate MCL at 0.010 mg/L. EPA believes that this is a prudent step at this time, which will preserve microbial protection. EPA will also analyze any new health effects data available on bromate. It is possible that EPA may determine that the bromate MCL should be decreased to 0.005 mg/L or lower.

The Stage 2 M-DBP Advisory Committee also discussed the problem of hypochlorite solutions contaminated with bromate. This contamination occurs during the production of hypochlorite solutions from natural salt deposits. The range of bromate concentrations in hypochlorite stock solutions varies widely (Bolyard et al., 1992; Chlorine Institute, 1999, 2000). Of course, the bromate contained in the stock solution is diluted upon addition to the drinking water. From data on ICR ozone systems that used hypochlorite versus those that used gaseous chlorine, the TWG estimated that hypochlorite solutions contributed approximately 0.001 mg/L bromate. The Advisory Committee discussed these results and determined that since the

bromate levels resulting from hypochlorite solutions was small compared to the MCL, there was no need to regulate bromate at all systems (i.e., non-ozone systems) using hypochlorite. They recognized that ozone systems using hypochlorite will have to be careful about the quality of their stock solution.

EPA agrees with the Advisory Committee determination and is therefore not proposing bromate monitoring requirements for non-ozone systems using hypochlorite.

3. Request for comment

EPA requests comment on the decision to maintain the Stage 1 DBPR bromate BAT and MCL of 0.010 mg/L. EPA also requests comment on the decision not to require bromate monitoring at non-ozone systems that use hypochlorite.

E. Initial distribution system evaluation (IDSE)

1. What is EPA proposing today?

In order to identify optimal sample locations for Stage 2 B TTHM and HAA5 MCL compliance monitoring, EPA is proposing requirements for systems (including consecutive systems) to perform an IDSE. Systems will either monitor for TTHM and HAA5 for one year at a number of sample points throughout their distribution system or perform a site-specific data study.

The IDSE was recommended by the Stage 2 M-DBP Advisory Committee. While the Advisory Committee only included community water systems in their IDSE recommendation, EPA believes that large nontransient noncommunity water systems (those serving at least 10,000 people) will have a distribution system that should be characterized by an IDSE. Therefore, EPA is proposing that such systems conduct an IDSE.

The objective of today's proposed rule is to reduce peak DBP levels in the distribution system. IDSEs are intended to select new compliance monitoring sites that better represent the highest concentrations of THMs and HAA5. See section V.F. of today's preamble and §141.10xx of the rule language for details on monitoring provisions and section V.G. of today's preamble and §141.10xx of the rule language for details on compliance schedules for the IDSE.

a. IDSE monitoring

For those systems that conduct monitoring to meet the IDSE requirement, the frequency and number of samples required is determined by source water type and system size (see section V.F. for specific monitoring requirements). Systems will monitor for one year on a regular schedule at sites throughout their distribution system. EPA will provide guidance on selecting IDSE monitoring sites and conducting IDSE monitoring (see section I.5.). As a part of the monitoring schedule, all systems conducting IDSE monitoring must monitor during the peak historical month for TTHM levels (or water temperature when quarterly TTHM data is not available). All IDSE samples must be paired (i.e., a TTHM and a HAA5 sample will be taken at each site). The IDSE monitoring results will not be used for determining compliance with MCLs but must be reported in the Consumer Confidence Report.

Systems conducting IDSE monitoring may do so over any annual period within the first 24 months after rule promulgation. It is up to the system to allocate enough time in their IDSE schedule to prepare their report to the State following the completion of their distribution system monitoring or data analysis.

b. IDSE site-specific studies submitted in lieu of monitoring

In order to comply with the IDSE requirement, in lieu of distribution system monitoring, systems may perform a system-specific study based on other monitoring studies or data. These alternative studies must provide equivalent or better information for selecting new monitoring sites that target high TTHM and HAA5 levels. Examples of alternative studies are recent site-specific monitoring data that encompass a wide range of sample sites, including those judged to target high TTHM and HAA5 concentrations and hydraulic monitoring studies that cover a large percentage of the distribution system. Historical TTHM and HAA5 results submitted by systems must come from certified labs and must include the system's most recent data. Treatment plant and distribution system characteristics at the time of historical data collection must reflect the current plant and distribution system. EPA is developing guidance on IDSE alternative system-specific studies and determining whether site-specific data could be sufficient to meet the IDSE requirements (see section I.5.).

c. IDSE waiver for systems serving fewer than 500

The IDSE requirement for systems serving fewer than 500 people may be waived if the State determines that the monitoring site approved for Stage 1 DBPR compliance is sufficient to represent both the highest HAA5 and the highest TTHM concentrations. The State must submit criteria for this determination to EPA as part of their primacy application. States may decide to waive the IDSE requirement for all systems serving fewer than 500 or some subset of all systems serving fewer than 500 if the State determines that it is appropriate to do so (EPA will provide guidance to States on situations for which a waiver would not be advisable). In cases where

States have not granted across-the-board waivers or have not notified systems regarding their waiver status, individual systems may request a waiver from the State.

d. IDSE out for systems with low DBP levels

Systems that certify to their state that all properly analyzed samples (i.e., analyzed by certified labs) taken in the two years prior to the start of the IDSE, under an appropriate sampling plan, were $\leq$ 0.040 mg/L TTHM and 0.030 mg/L HAA5 are not required to conduct IDSE monitoring or a site-specific study.

Some systems may already be on reduced monitoring for the Stage 1 DBPR during the two years prior to the start of the IDSE. However, the requirements for going to reduced monitoring ($\leq$ 0.040 mg/L TTHM and 0.030 mg/L HAA5 as RAAs) are less stringent than the requirements to get out of the IDSE (all samples must be $\leq$ 0.040 mg/L TTHM and 0.030 mg/L HAA5). In addition, those systems on reduced monitoring collect samples only at the maximum residence time, which may not always capture the system's highest TTHM or HAA5 levels. Because of these problems, EPA is proposing that data submitted to meet the IDSE out criteria must include the most recent year of routine monitoring conducted at a regular frequency (i.e., systems may submit more than 2 years of data). The data set submitted for this requirement must be complete (i.e., no monitoring violations).

Although many ground water systems have low DBP levels, due to the timing of the Stage 1 DBPR and the IDSE requirements, many large ground water systems may not have two years of HAA5 data to submit. Thus, EPA is proposing that instead of two years worth of data demonstrating $\leq$ 0.040 mg/L TTHM and 0.030 mg/L HAA5, large ground water systems that lack sufficient HAA5 data, may submit two years worth of data demonstrating $\leq$ 0.040 mg/L

TTHM and a set of simulated distribution system (SDS) tests for HAA5. One SDS test must be held for the average distribution system residence time for the plant and another for a period representing the maximum distribution system residence time for the plant. The SDS tests must be conducted during the month that historically had the warmest water temperature. See §141.10xx of the rule language for more detail on the SDS requirements. If a system measures >30 Fg/L HAA5 in any of their SDS tests, the system must conduct either IDSE monitoring or a site-specific study.

The Stage 2 MCL compliance monitoring sites recommended by the Advisory Committee and proposed today have fundamentally different objectives than the Stage 1 DBPR monitoring sites (i.e., the Stage 2 sites target the highest TTHM and HAA5 levels). In addition, many systems are required to have more Stage 2 compliance monitoring sites than Stage 1 sites. For these reasons, even systems that qualify for an IDSE out, based on low DBP occurrence, must prepare a Stage 2 DBPR compliance sampling plan based on the monitoring provisions in V.F. of today's preamble and §141.10xx of the rule language. EPA will recommend criteria that systems not conducting an IDSE can use to select their new Stage 2 DBPR compliance monitoring sites in guidance.

e. IDSE reports

All systems, with the exception of systems serving less than 500 people that receive an IDSE waiver, must submit an IDSE report to the State. The IDSE report must include (see § 141.1015 of today's rule):

- all IDSE TTHM and HAA5 analytical results (for systems that conduct IDSE monitoring);

- any analytical results or modeling (for systems that conduct an IDSE site-specific study);
- data demonstrating that all samples are ≤ 0.040 mg/L TTHM and all samples (or SDS tests for large ground water systems with insufficient HAA5 data) are ≤ 0.030 mg/L HAA5 (for systems that qualify for the IDSE out);
- all TTHM and HAA5 analytical results from compliance monitoring conducted during the period of the IDSE;
- a schematic of the distribution system (with results, location, and date of all samples noted);
- the original IDSE monitoring plan and an explanation of any deviations from that plan;
- and recommendations for TTHM and HAA5 Stage 2 DBPR compliance monitoring sites.

A system must recommend locations with the highest LRAAs unless it provides a rationale for selecting other locations (see § 141.1016 of today's rule). Systems must consider both their compliance data and the IDSE data in making this determination. EPA will provide guidance for selecting new monitoring sites and preparing the IDSE report.

Systems serving ≥10,000 must submit their report 24 months after rule promulgation (see §141.10xx of the rule). These systems will thus be conducting their IDSE prior to State primacy. Systems may use the EPA guidance manual for assistance. Systems serving <10,000 must submit their report 48 months after rule promulgation (see §141.10xx of the rule). At the time that these systems conduct their monitoring or analyze their site-specific data, States will have primacy. These systems, therefore, will be able to rely on both the guidance manual and the State for assistance. If consecutive systems serving < 10,000 buy water from a system that serves 10,000 or more people, then this consecutive system must comply within the same

schedule as that for systems > 10,000 (i.e., complete the IDSE within 24 months after promulgation). If the wholesaler serves < 10,000 but sells water to a consecutive system serving > 10,000, then both the wholesaler and the consecutive system must complete the IDSE within 24 months after promulgation.

States will specify requirements for systems that do not submit an IDSE report to the State or that have not, in the determination of the State, conducted an adequate IDSE. The State requirements may include repeating the IDSE while conducting compliance monitoring at Stage 1 monitoring sites or conducting Stage 2 compliance monitoring at sites selected by the State.

2. How was this proposal developed?

a. Consideration of approach to decrease peak DBP levels

Many members of the M-DBP Advisory Committee believed that allowing utilities to maintain their Stage 1 DBPR sampling sites for the Stage 2 DBPR would not accomplish the objective of decreasing peak DBP levels in the distribution system. The intent of the Stage 1 DBPR sampling sites was to capture a representative sample of DBPs within the distribution system, not necessarily maximum DBP levels. The Committee thus devised the IDSE, in which all systems will either increase the number and frequency of TTHM and HAA5 samples for one year or analyze site-specific data in order to determine new monitoring sites. Subsequent compliance monitoring at these new sites will reduce DBP peaks in the distribution system and associated potential health effects. The Committee recommended a number of sample locations (based on distribution system residual disinfectant type) that were chosen such that the IDSE monitoring would occur at widely distributed sites (see section V.F. for details on IDSE monitoring requirements). Scattering IDSE monitoring sites across the distribution system

increases the chance of discovering DBP peak sites and targets both DBPs that degrade, and DBPs that form, as residence time increases in the distribution system.

EPA believes that the IDSE requirement is an important component of the Stage 2 DBPR for all systems (including consecutive systems). The IDSE monitoring is a one-time requirement to target the sites in the distribution system with the highest TTHM and HAA5 levels. New Stage 2 DBPR compliance monitoring sites will be established following an analysis of the IDSE results. EPA believes that States will address future distribution system changes and the need for shifts in compliance monitoring sites that may result from these changes.

The frequency and number of samples required for compliance with IDSE monitoring decrease as system size (population served) decreases and depend on source water type. The Committee believed that the number of samples required for large and medium surface water systems was not necessary for small surface water systems and ground water systems. The majority of small systems have distribution systems with simpler designs than large systems. DBP formation in ground water systems is generally less variable than in surface water systems due to the uniformity of their supply and much less temperature variation.

Committee members recognized that some systems have detailed knowledge of their distribution systems by way of hydraulic modeling and/or ongoing widespread monitoring plans throughout their distribution systems. Therefore, the Advisory Committee recommended that such systems, be allowed to determine new monitoring sites using site-specific data such as historical monitoring data that provide equivalent or superior site selection.

Under the Stage 1 DBPR small systems are required to collect samples at a site representative of maximum residence time. Very small systems (those serving less than 500)

typically have small distribution systems and the maximum residence time site is likely to capture both the high TTHM and high HAA5 levels within the distribution system (i.e., the HAA5 may not degrade prior to the site). Thus, the Advisory Committee recommended that States be allowed to grant IDSE waivers to systems serving less than 500. The Committee recognized that not all of these systems had distribution systems configured such that the maximum residence time would capture the high HAA5.

Systems that certify to their State that all properly analyzed samples taken in the two years prior to the start of the IDSE, under an appropriate sampling plan, were $\leq$ 0.040 mg/L TTHM and 0.030 mg/L HAA5 are not required to conduct the IDSE because the Advisory Committee determined that these systems most likely would not produce high DBP peaks. However, after the conclusion of the Stage 2 M-DBP negotiations, EPA determined that this provision needed to be more specific for two groups of systems, those on reduced monitoring and large ground water systems. The requirement for reduced monitoring is less stringent than the requirement to get out of the IDSE. In addition, systems on reduced monitoring collect samples only at the maximum residence time, which may not always capture the system's high TTHM or HAA5 levels. Because of these problems, EPA is proposing that data submitted to meet the IDSE out criteria must include the most recent year of routine monitoring. Many large ground water systems may not have two years of HAA5 data to submit. Thus, EPA is proposing that large ground water systems may submit two years worth of data demonstrating $\leq$ 0.040 mg/L TTHM and a set of SDS tests for HAA5. Systems serving $\geq$10,000 must submit their IDSE report 24 months after rule promulgation (which is prior to State primacy). The M-DBP Advisory Committee recommended an implementation schedule which would allow utilities

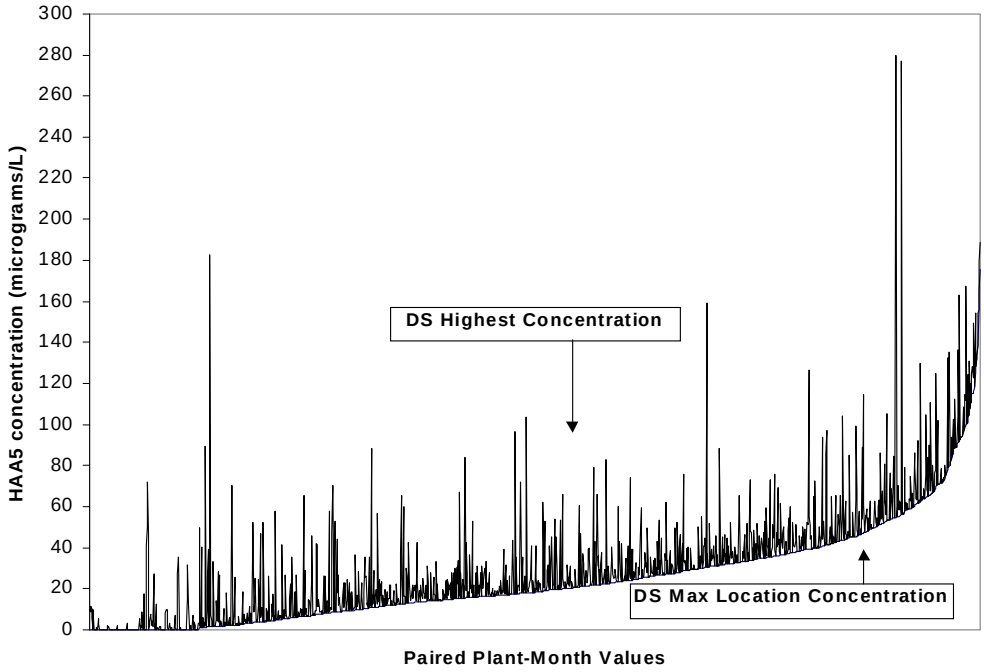
sufficient time to make site specific risk determinations and decisions regarding the simultaneous implementation of the Stage 2 DBPR and LT2ESWTR but not stretch out the compliance time frame too far into the future. The Advisory Committee thus determined that for medium and large systems, site specific risk determinations (i.e., the IDSE and LT2ESWTR *Cryptosporidium* monitoring) should be done as soon as possible after rule promulgation. Since small systems are not required to begin their microbial monitoring until after the results from the large system microbial monitoring have been compiled, small systems have a longer compliance time frame.

b. Basis for the IDSE

The IDSE is designed to target both high TTHM and high HAA5 sites (see section V.F. for IDSE monitoring site locations). TTHM and HAA5 occurrence often peak at different points in the distribution system. The Stage 1 DBPR monitoring locations identified as the maximum location are selected according to residence time. The ICR data shows that monitoring locations identified as the maximum residence time locations were often not the locations where the highest DBP levels were found. Because HAAs can degrade in the distribution system, residence time is not an ideal criteria for identifying high HAA5 sites. The ICR data demonstrated that the highest HAA5 concentration could be at any of the four ICR sample locations in the plant's distribution system or, in some cases, at the finished water location. Some of the ICR HAA5 data reflected sample periods where all four distribution system concentrations were lower than the concentration measured in the finished water. Figure V.6. shows the HAA5 concentration for the maximum residence time distribution system location and the distribution system highest value (any one of the four sampled locations), in the ICR data. As can be seen in the figure, the highest value in the distribution system does not always

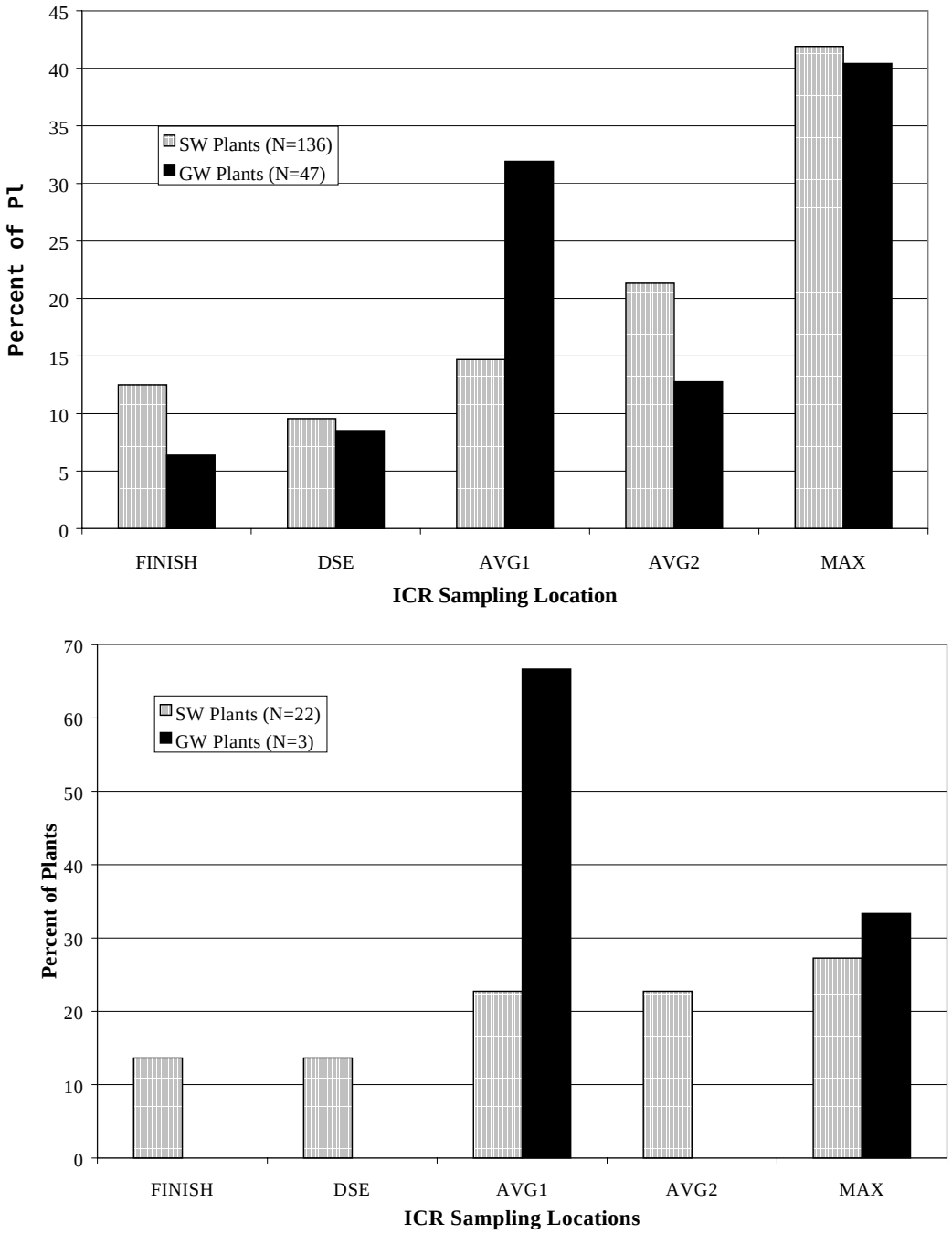
correspond to the distribution system maximum residence time sampling location for a given sample event. In fact, 65 percent of ICR distribution system highest HAA5 data occurred at one of the other three sampling locations.

Figure V.6. Comparison of the highest HAA5 level in the distribution system to the corresponding HAA5 level at the distribution system maximum residence time sample location.(data from last 4 quarters of ICR data)



For the subset of plants that had sufficient data, approximately 60% of the highest HAA5 LRAAs did not occur at the location having the maximum residence time (Figure V.7.a.). For those plants with HAA5 LRAAs greater than 48 μg/L, over 70% of the highest LRAAs were not at the location of maximum residence time (Figure V.7.b.).

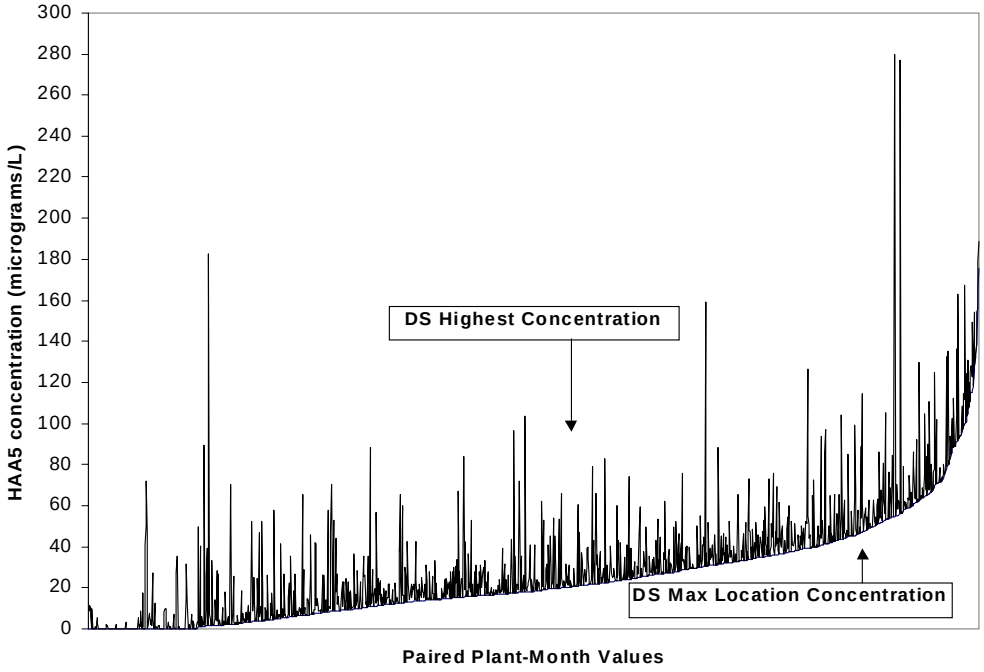
Figure V.7. a. Frequency at which the highest HAA5 LRAA occurred at each ICR sampling location. [1] **b.** Frequency for systems with LRAAs $\geq$ 48 µg/L. [1]



[1] Based on last 4 quarters of ICR data for the subset of plants with valid data at each location for each quarter.

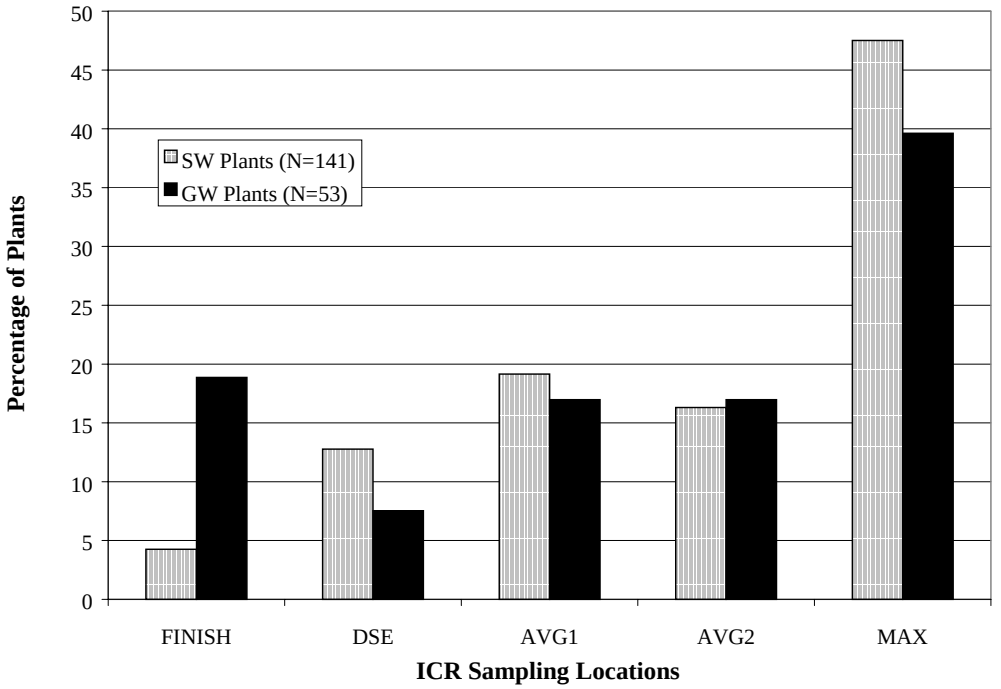
It is also evident from the ICR data that the highest TTHM levels are not always located at the maximum residence time monitoring location sites (Figure V.8.). In fact, 49 percent of ICR distribution system highest TTHM data occurred at one of the other three sampling locations.

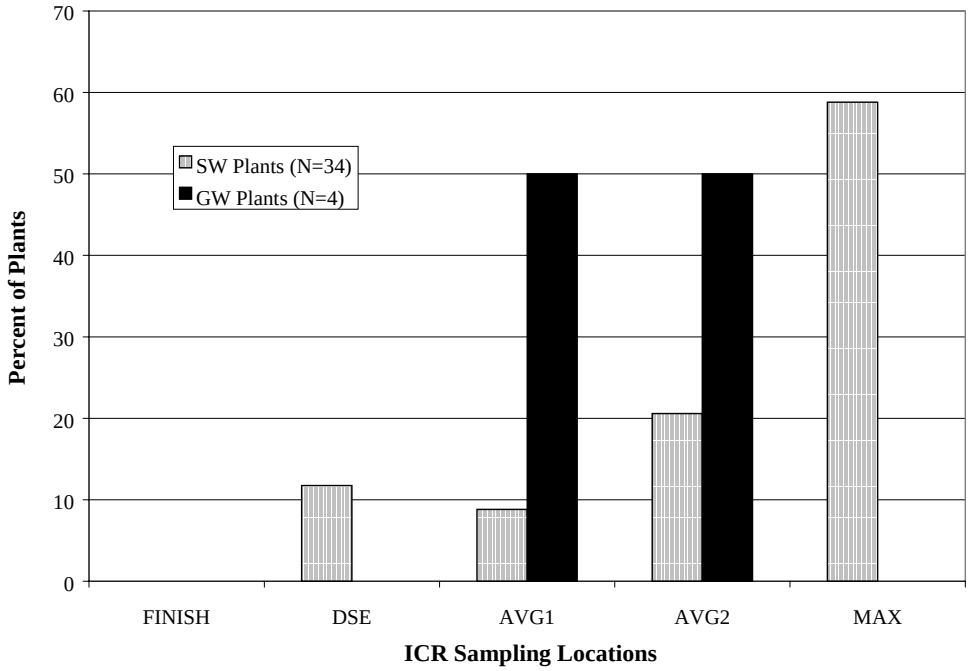
Figure V.8. Comparison of the highest TTHM level in the distribution system to the corresponding TTHM level at the distribution system maximum sample location (data from last 4 quarters of ICR data).



For the subset of plants that had sufficient data, over 50% of the highest TTHM LRAAs did not occur at the maximum residence time monitoring location (Figure V.9.a.). For those plants with TTHM LRAAs greater than 64 μg/L, over 40% of the highest LRAAs were not at the maximum residence time monitoring site (Figure V.9.b.).

Figure V.9. a. Frequency at which the highest TTHM LRAA occurred at each ICR sampling location. [1] **b.** Frequency for plants with LRAAs ≥ 64 µg/L [1]





[1] Based on last 4 quarters of ICR data for the subset of plants with valid data at each location for each quarter.

This data analysis reveals that a reevaluation of monitoring sites is necessary at many plants. With a recharacterization of distribution systems that focuses on *both* high TTHM and HAA5 occurrence points, EPA believes that high occurrence sites will be better represented in monitoring data. Thus, systems will be required to take steps to address high DBP levels at points that might otherwise have gone undetected. EPA believes that the decrease in DBP levels anticipated to result from the transition from an RAA to an LRAA, as a result of the proposed rule, will be augmented by the IDSE.

3. Request for comment

EPA requests comments on the IDSE requirement and whether it is a good tool to identify sites representative of high TTHM and high HAA5 levels. EPA also requests comment on the requirements for those systems conducting IDSE monitoring. EPA solicits comments on the proposal to allow systems to submit a site-specific data study in lieu of monitoring and the allowance of IDSE waivers for systems serving less than 500 people. EPA also requests comment on the proposal that systems with low TTHM and HAA5 to be exempt from conducting either IDSE monitoring or a site-specific study. EPA requests comment on the IDSE out provisions for systems on reduced monitoring. EPA also requests comment on the alternative IDSE out provisions for large ground water systems and on the proposed SDS conditions.

EPA requests comment on the requirements for the contents of IDSE reports. EPA solicits opinion on the proposed method of Stage 2 DBPR site selection.

EPA requests comment on the requirement that large and medium systems must perform their IDSE prior to State primacy. EPA requests comments from the States regarding whether or not they want to be involved in those IDSEs that will occur prior to primacy.

EPA requests comment on the decision to leave future reevaluations of Stage 2 DBPR compliance monitoring sites up to the discretion of the States.

F. Monitoring requirements and compliance determination

1. What is EPA proposing?

EPA is proposing monitoring requirements to support implementation of the new MCL requirements for TTHM and HAA5 and implementation of the IDSE. EPA is also proposing to revise conditions for reduced bromate monitoring. Monitoring must be conducted during normal operating conditions. Failure to monitor in accordance with the monitoring plan is a monitoring violation. A system's failure to monitor that makes it impossible to determine compliance with MCLs based on a locational running annual average of quarterly samples will be treated as a monitoring violation for the four quarters that those results would have been used to determine an LRAA had they been available. A system's failure to perform an IDSE (either monitoring or site-specific data study) that makes it impossible to determine new sample sites for compliance with the long-term MCLs will be treated as a monitoring violation.

For Stage 2A of this rule, systems will not be required to conduct any new monitoring. They will continue to monitor at Stage 1 DBPR (subpart L) locations. However, in addition to calculating compliance with the Stage 1 TTHM and HAA5 MCLs (as a running annual average), systems will be required to calculate compliance with the Stage 2A transitional MCL as locational running annual averages of 0.120 mg/L for TTHM and 0.100 mg/L for HAA5 for each Stage 1 DBPR monitoring location. Generally, this requirement will only affect subpart H systems serving at least 10,000 people or systems with multiple plants, since they are the only ones required to monitor at more than one location in the distribution system.

All other systems are required to take compliance samples at only one location under Stage 1 and their LRAA would be equal to their RAA. However, any system that conducts compliance monitoring (as identified in the monitoring plan required by the Stage 1 DBPR) at more than one location (including those that are monitoring in excess of routine requirements) must comply with the Stage 2A LRAAs.

During Stage 2A, systems which have a TTHM RAA $\leq$ 0.040 mg/L and a HAA5 RAA $\leq$ 0.030 mg/L may reduce the monitoring frequency for TTHM and HAA5 to one sample per treatment plant at a site representative of maximum residence time. Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the RAA of all samples taken in the year is no more than 0.060 mg/L for TTHM and 0.045 mg/L for HAA5. Systems must revert to routine monitoring in the quarter immediately following any quarter in which they exceed 0.060 mg/L for TTHM or 0.045 mg/L for HAA5. Additionally, the State may return a system to routine monitoring at the State's discretion.

As recommended by the Advisory Committee, the monitoring for Stage 2B is structured so that systems that monitor quarterly under the Stage 1 DBPR will continue to monitor approximately every 90 days. In addition, the monitoring schedule must include the month with the highest historical DBP concentrations. These provisions prevent systems from monitoring for DBPs in a way that minimizes high readings. The 1979 TTHM rule and the Stage 1 DBPR required systems to monitor at quarterly intervals. The spirit of this requirement is that systems would monitor every three months. However, some systems chose to cluster samples during times of the year when DBP levels are lowest (during cold weather DBPs tend to form more slowly). For example, a system may sample in December (at the end of the fourth quarter) and

again in January (at the beginning of the first quarter) when the water is the coldest and sample in April (at the beginning of the second quarter) and September (at the end of the third quarter) at either end of the hot summer months. Therefore, EPA is proposing to require systems to monitor during the month of highest historical DBP concentrations and require that systems monitor approximately every 90 days. EPA believes that this new monitoring strategy will improve public health protection because systems will be required to monitor during peak occurrence periods.

Tables V-3 and V-4 below summarize routine and reduced monitoring requirements for Stage 2B of today's rule.

Table V-3. Proposed Stage 2B routine monitoring requirements[1]

REQUIREMENT (reference)	**SURFACE WATER SYSTEMS (≥ 10,000)**	**SURFACE WATER SYSTEMS (500 - 9,999) & GROUND WATER SYSTEMS[2,3] (≥ 10,000)**	**GROUND WATER SYSTEMS[2,3] (500 - 9,999)**	**SURFACE WATER SYSTEMS (< 500) & GROUND WATER SYSTEMS[2,3] (< 500)**
Stage 2B TTHM and HAA5	4 sites/plant/quarter: one at dist system representative location, one at highest HAA5 location, two at highest TTHM location.[5]	2 sites[6]/plant/quarter: one at highest HAA5 location, one at highest TTHM location.[5]	2 sites[6]/plant/ year[4]: one at highest HAA5 location, one at highest TTHM location[5] during warmest month	1 site[7]/plant/year[4]: at highest HAA5 and TTHM location[5] during warmest month

[1] Samples must be taken during representative operating conditions. For summary of reduced monitoring provisions see Table V-X. Quarterly samples must be taken approximately every 90 days. The State may modify sampling locations.
[2] Systems using ground water not under the direct influence of surface water.
[3] For the purpose of determining the minimum number of samples, multiple wells drawing water from a single aquifer may, with State approval, be considered one treatment plant.
[4] If the annual monitoring result exceeds the MCL, the system must increase monitoring frequency to 1/plant/quarter. Compliance determinations will be based on the RAA/LRAA of quarterly monitoring results.
[5] Systems will use the results of their IDSEs to select new monitoring sites representative of highest TTHM and HAA5 levels.
[6] If the State determines that the highest TTHM site and the highest HAA5 site are at the same location, the system may monitor at 1 site/plant.
[7] If the State determines that the highest TTHM site and the highest HAA5 site are not at the same location, the system is required to monitor at 2 sites/plant/quarter (unpaired samples).

Table V-4. Proposed reduced monitoring requirements[1,2]

REQUIREMENT (reference)	**SURFACE WATER SYSTEMS (≥ 10,000)[3]**	**SURFACE WATER SYSTEMS (500 - 9,999)[3] & GROUND WATER SYSTEMS (> 10,000)**	**GROUND WATER SYSTEMS (<10,000)**
Stage 2B TTHM and HAA5	IF 1) system has completed at least 1 yr of routine or IDSE monitoring and 2) all TTHM and HAA5 locational running annual averages are no more than 0.040 mg/l and 0.030 mg/l, respectively.		IF 1) system has completed at least 2 yr of routine or IDSE monitoring and 2) all TTHM and HAA5 locational running annual averages are no more than 0.040 mg/l and 0.030 mg/l, respectively OR 1) system has completed at least 1 yr of routine or IDSE monitoring and 2) all TTHM and HAA5 locational running annual averages are no more than 0.020 mg/l and 0.015 mg/l, respectively.
	2 sites/plant/qtr, one at highest HAA5 location, one at highest TTHM location.	2 sites[4]/plant/ year: one at highest HAA5 location, one at highest TTHM location during month of highest TTHM and HAA5 single measurements.	2 sites[5]/plant/3yr: one at highest HAA5 location, one at highest TTHM location, during month of warmest water temperature.

[1] Samples must be taken during representative operating conditions. For summary of routine monitoring provisions see Table V-X.
[2] Requirements for cancellation of reduced monitoring are found in the regulation.
[3] Monitoring cannot be reduced if subpart H system source water TOC > 4.0 mg/l.
[4] If the State determines that the highest TTHM site and the highest HAA5 site are at the same location, the system may monitor at 1 site/plant/year.
[5] For ground water systems <500: 1 site/plant/3 yrs at highest HAA5 & TTHM location unless the State determines that the highest TTHM site and the highest HAA5 site are not at the same location. If so, the system is required to collect unpaired samples at 2 sites/plant/3 yrs during month of warmest water temperature.

DBP levels are affected by the type and amount of disinfectant used, water temperature, pH, amount and type of precursor material in the water, and the length of time that water remains in the treatment and distribution systems. For this reason, today's rule proposes the sampling schedule and specifies points in the distribution system where samples must be taken. For purposes of determining the minimum number of samples, EPA proposes to maintain the provision in the Stage 1 DBPR (§141.132(a)(2)) that multiple wells drawing raw water from a single aquifer may, with State approval, be considered one plant.

a. IDSE

IDSE monitoring results will not be used for Stage 1 DBPR or Stage 2 DBPR compliance purposes. Subpart H systems serving ≥10,000 people are required to conduct IDSE monitoring bimonthly, approximately every 60 days, at eight distribution system sites per plant (at sites that are in addition to Stage 1 DBPR compliance monitoring sites). The location of the eight sites will be determined by distribution system residual disinfectant type as shown in Table V-5. Surface water systems serving 500 – 9,999 people and ground water systems serving ≥10,000 people are required to conduct IDSE monitoring quarterly, approximately every 90 days; subpart H systems serving <500 people and ground water systems serving <10,000 people are required to conduct IDSE monitoring semi-annually, approximately every 180 days. Surface water systems serving fewer than 10,000 people and all ground water systems must monitor at two distribution system sites per plant (at sites that are in addition to the Stage 1 DBPR compliance monitoring sites) as defined in Table V-5, with the exception of some systems serving under 500 people. The Advisory Committee recommended these sites be based on analysis of ICR data and the residual disinfectant used.

Table V-5. Proposed IDSE monitoring requirements

Source Water Type : System Size	Distribution System Disinfectant Type	Distribution System Sample Location			
		Near Entry Point	Average Residence Time	Highest TTHM Points	Highest HAA5 Points
Subpart H $10,000	Chloramines	2	2	2	2
	Chlorine	1	2	3	2
Subpart H 500 - 9,999 OR Ground Water $10,000	Any	0	0	1	1
Subpart H <500 OR Ground Water 500 - 9,999	Any	0	0	1	1

As a part of the monitoring schedule, all systems conducting IDSE monitoring must monitor during the peak historical month for TTHM levels or water temperature. All IDSE samples must be paired (i.e., a TTHM and a HAA5 sample will be taken at each site). EPA will provide guidance to assist systems in choosing IDSE monitoring locations.

b. Stage 2B TTHM and HAA5 MCL compliance monitoring

EPA is proposing to require all systems to develop a monitoring plan that must include the following information: monitoring locations, monitoring dates, compliance calculation procedures, monitoring plans for other systems in a combined distribution system, and copies of any permits, contracts, or other agreements with third parties to sample, analyze, report, or perform any other system requirement. Systems may elect to simply update the monitoring plan required under the Stage 1 DBPR (see §141.132(f)). The system must follow the monitoring

plan, which will be based on the IDSE report submitted to the State, modified by any changes required by the State.

Systems must also begin Stage 2B on routine monitoring (i.e., without any reduced monitoring). They may qualify for reduced monitoring after the criteria for reduced monitoring have been met based on samples taken at Stage 2B monitoring sites.

i. Subpart H systems serving 10,000 or more people

Routine Monitoring: CWSs and NTNCWSs using surface water or ground water under direct influence of surface water (subpart H systems) that treat their water with a chemical disinfectant (or deliver water that has been treated with a chemical disinfectant) and serve ≥10,000 people must take four water samples per treatment plant each quarter for both TTHM and HAA5. One sample must be taken at the existing Stage 1 DBPR monitoring location with the highest TTHM or HAA5 LRAA, one sample must be taken at a point representative of the highest HAA5 levels (as identified under the IDSE report), and two samples must be taken at a point representative of the highest TTHM levels (as identified under the IDSE report).

Monitoring must be scheduled so that one quarterly sample is taken during the peak historical month for TTHM and other quarterly samples taken approximately every 90 days, on a predetermined schedule included in the system's monitoring plan. All samples must be paired (i.e., a TTHM and a HAA5 sample must be taken at each site).

Reduced Monitoring: Only systems with source water TOC ≤ 4.0 mg/L as a RAA that have completed at least one year of routine monitoring may qualify for reduced monitoring (see Figure V-X). Systems that have a TTHM LRAA ≤ 0.040 mg/L and a HAA5 LRAA ≤ 0.030 mg/L at all sites, in addition to a TOC RAA ≤ 4.0 mg/L, may reduce the monitoring frequency

for TTHM and HAA5 to two samples (one each at sites representative of the highest HAA5 and TTHM LRAAs) per treatment plant per quarter. As with the routine monitoring, the sampling schedule must include the quarter with the peak historical TTHM levels. Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the LRAA of all samples taken in the year is no more than 0.040 mg/L for TTHM and 0.030 mg/L for HAA5. Systems must revert to routine monitoring in the quarter immediately following any quarter in which the LRAA for any monitoring location exceeds 0.040 mg/L for TTHM or 0.030 mg/L for HAA5. Additionally, the State may return a system to routine monitoring at the State's discretion.

Compliance Determination: A PWS is in compliance with Stage 2B when the locational running annual average of each sample location, computed quarterly, is less than or equal to the MCL. Otherwise, the system is out of compliance.

Figure V-10. Eligibility for reduced TTHM and HAA5 monitoring: ground water systems serving ≥10,000 people and subpart H systems serving ≥ 500 people

Systems must meet **all** of the following conditions:

- The LRAA for TTHM is ≤ 0.040 mg/L at all monitoring locations.
- The LRAA for HAA5 is ≤ 0.030 mg/L at all monitoring locations.
- At least one year of routine monitoring has been completed.
- Annual average source water TOC level is ≤ 4.0 mg/L prior to treatment (applies to subpart H systems only).

ii. Subpart H systems serving 500 to 9,999 people

Routine Monitoring: Subpart H systems that treat their water with a chemical disinfectant or deliver water that has been treated by a chemical disinfectant and serve 500 to 9,999 people must monitor quarterly for each treatment plant. Systems are required to take two water samples, one each at sites representative of the highest HAA5 levels and the highest TTHM levels (as identified under the IDSE requirement). However, if the State determines that the sites

representative of the highest TTHM and HAA5 levels are the same, the State may determine that the system is only required to monitor at one site per treatment plant.

One quarterly sample must be taken during the peak historical month for TTHM or water temperature levels and other quarterly samples taken approximately every 90 days, on a predetermined schedule specified in the system's monitoring plan. All samples must be paired (i.e., a TTHM and a HAA5 sample must be taken at each site).

Reduced Monitoring: To qualify for reduced monitoring, systems must meet certain prerequisites (see Figure V-10). Systems eligible for reduced monitoring may reduce the monitoring frequency from quarterly to annually. Samples must be taken during the month(s) of peak historical TTHM and HAA5 levels at the same locations specified under routine monitoring. Systems that have their highest TTHM and HAA5 levels in the same month must take one paired sample at both the high TTHM and high HAA5 sites. If the high months for TTHM and HAA5 are not the same, the system must take paired samples in both the high TTHM and high HAA5 months. Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the annual sample taken at each location is no more than 0.060 mg/L for TTHM and 0.045 mg/L for HAA5. Systems that do not meet these levels must revert to routine monitoring in the quarter immediately following the quarter in which the system exceeded 0.060 mg/L for TTHM or 0.045 mg/L for HAA5. Additionally, the State may return a system to routine monitoring at the State's discretion.

Compliance Determination: A PWS is in compliance with Stage 2B when the locational running annual arithmetic average of each sample location, computed quarterly, is less than or equal to the MCL. Otherwise, the system is out of compliance.

iii. Subpart H systems serving fewer than 500 people

Routine Monitoring: Subpart H systems that treat their water with a chemical disinfectant or deliver water that has been treated by a chemical disinfectant and serve fewer than 500 people are required to sample annually for each treatment plant at the points of highest TTHM and HAA5 values during the month of peak historical TTHM levels. Systems are required to take one water sample at the site representative of the highest HAA5 and TTHM levels (as identified under the IDSE requirement) unless the State determines that the highest TTHM site and the highest HAA5 site are not at the same location or during the same quarter. If the State makes this determination, the system is required to take two unpaired water samples, an HAA5 sample at the site representative of the highest HAA5 levels and a TTHM sample at the site representative the highest TTHM levels. If the annual sample exceeds the MCL for either TTHM or HAA5, the system must increase monitoring to one sample per treatment plant per quarter, taken at each monitoring location in the distribution system.

Reduced Monitoring: These systems may not reduce monitoring. Systems on increased (quarterly) monitoring may return to routine monitoring if the LRAAs of quarterly samples are no more than 0.060 mg/L for TTHM and 0.045 mg/L for HAA5.

Compliance Determination: A PWS is in compliance when the annual sample (or LRAA of annual samples, if additional sampling is conducted) is less than or equal to the MCL. If the annual sample exceeds the MCL, the system must conduct increased (quarterly) monitoring. The system is out of compliance if the LRAA of the quarterly samples exceeds the MCL.

iv. Ground water systems serving ≥10,000

Routine Monitoring: CWSs and NTNCWSs using ground water sources that treat their water with a chemical disinfectant or deliver water that has been treated by a chemical disinfectant and serve 10,000 or more people are required to sample quarterly for each treatment plant in the system. Systems are required to take two water samples, one each at sites representative of the highest HAA5 levels and the highest TTHM levels (as identified under the IDSE requirement). However, if the State determines that the sites representative of the highest TTHM and HAA5 levels are the same, the State may determine that the system only has to monitor at one site per treatment plant.

One quarterly sample must be taken during the peak historical month for TTHM, with subsequent quarterly samples taken approximately every 90 days. All samples must be paired (i.e., a TTHM and a HAA5 sample must be taken at each site).

Reduced Monitoring: To qualify for reduced monitoring, systems must meet certain prerequisites (see Figure V-10). Systems eligible for reduced monitoring may reduce the monitoring frequency from quarterly to annually. Samples must be taken during the month(s) of peak historical TTHM and HAA5 levels at the same locations specified under routine monitoring. Systems that have their highest TTHM and HAA5 levels in the same month must take one paired sample at both the high TTHM and high HAA5 sites. If the high months for TTHM and HAA5 are not the same, the system must take paired samples in both the high TTHM and high HAA5 months. Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the annual sample taken at each location is no more than 0.060 mg/L for TTHM and 0.045 mg/L for HAA5. Systems that do not meet these levels must revert to routine

monitoring in the quarter immediately following the quarter in which the system exceeded 0.060 mg/L for TTHM or 0.045 mg/L for HAA5. Additionally, the State may return a system to routine monitoring at the State's discretion.

Compliance Determination: A PWS is in compliance with Stage 2B when the locational running annual arithmetic average of each sample location, computed quarterly, is less than or equal to the MCL. Otherwise, the system is out of compliance.

v. Ground water systems serving fewer than 10,000 people

Routine Monitoring: CWSs and NTNCWSs using only ground water sources not under the direct influence of surface water that treat their water with a chemical disinfectant or deliver water that has been treated with a chemical disinfectant and serve fewer than 10,000 people are required to sample annually for each treatment plant in the system.

Systems serving 500 to 9,999 people are required to take two paired water samples, one each at sites representative of the highest HAA5 levels and the highest TTHM levels (as identified under the IDSE requirement). However, if the State determines that the sites representative of the highest TTHM and HAA5 levels are the same, the State may determine that the system only has to monitor at one site per treatment plant.

Systems serving fewer than 500 people are required to take one water sample at the site representative of the highest HAA5 and TTHM levels (as identified under the IDSE requirement) unless the State determines that the highest TTHM site and the highest HAA5 site are not at the same location. If the State makes this determination, the system is required to take two unpaired water samples, an HAA5 sample at the site representative of the highest HAA5 levels and a TTHM sample at the site representative the highest TTHM levels. If a system

exceeds the MCL in its annual sample, the system must increase monitoring to quarterly. If the State makes a determination that high TTHM and high HAA5 occur in different months, the system must monitor accordingly.

Reduced Monitoring: To qualify for reduced monitoring, systems must meet certain prerequisites (see Figure V-11). Systems eligible for reduced monitoring may reduce the monitoring frequency for TTHM and HAA5 to every third year. Systems are required to take either one or two water samples, at sites representative of the highest HAA5 and TTHM levels (as discussed under routine monitoring) during the month of peak TTHM or water temperature levels. Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the sample taken every third year is no more than 0.040 mg/L for TTHM and 0.030 mg/L for HAA5. Systems that do not meet these levels must resume routine monitoring until their annual average is no more than 0.040 mg/L for TTHM and 0.030 mg/L for HAA5.

Compliance Determination: A PWS is in compliance when the annual sample (or average of annual samples) is less than or equal to the MCL.

Figure V-11. Eligibility for reduced TTHM and HAA5 monitoring: ground water systems serving fewer than 10,000 people.

Systems using ground water not under the direct influence of surface water that serve fewer than 10,000 people may reduce monitoring for TTHM and HAA5 if they meet **either** of the following conditions:

1. The LRAA of each of two consecutive annual samples for TTHM is no more than 0.040 mg/L, the LRAA of each of two consecutive annual samples for HAA5 is no more than 0.030 mg/L, and at least two years of routine monitoring has been completed.

2. The annual sample for TTHM is no more than 0.020 mg/L, the annual sample for HAA5 is no more than 0.015 mg/L, and at least one year of routine monitoring has been completed.

c. Consecutive systems

EPA is proposing that all wholesale and consecutive systems must comply with provisions of the Stage 2 DBPR on the same schedule required of the wholesale or consecutive system serving the largest population in the combined distribution system. However, the monitoring requirements are still determined by the consecutive system size and source water type of the wholesale system (unless the consecutive system also has a surface water or GWUDI source). There is a more complete discussion of consecutive system issues in section V.N. of today's notice.

2. Request for comments

EPA requests comments on the proposed monitoring requirements. Specifically:

- Should EPA limit eligibility for reduced monitoring during the IDSE monitoring period to systems that have already qualified for reduced monitoring?

- Should EPA require all systems to revert to routine monitoring during the IDSE monitoring period to allow for more data to be evaluated in the IDSE report to better select Stage 2B

monitoring locations? Or should EPA require a system to be on routine monitoring during the IDSE monitoring period in order to be eligible for an IDSE waiver?

- Should EPA allow or require systems to reallocate plant-based IDSE monitoring locations from small plants to large plants? From plants with better water quality (based on expected lower DBP formation) to poorer water quality?

EPA also requests comment on alternative DBP monitoring requirements that are population versus plant based. Today's proposal includes monitoring requirements that the FACA recommended in the Agreement in Principle. Many of these monitoring requirements were adopted from principles of the 1979 TTHM Rule and Stage 1 DBPR, i.e., the frequency of monitoring under the Stage 1 DBPR should be influenced by source water type (ground or surface water), size of system, and the number of plants per system. For Stage 2, as under Stage 1, the FACA recommended that both routine and additional DBP sampling be required on a plant basis, based on the assumption that as systems increase in size, they will tend to have more plants and increased complexity of treatment and distribution of water, thereby warranting increased monitoring to represent DBP occurrence in the distribution system. The FACA also recommended higher frequency monitoring for systems using surface water than those using ground water because ground waters tend to have lower and more stable concentrations of organic DBP precursors than surface waters. Furthermore, since many ground water systems have multiple wells/entry points drawing water from the same aquifer, the FACA recommended that all wells, coming from the same aquifer, could be considered as a single plant with the same monitoring requirements prescribed for one plant, if approved by the State (as allowed under Stage 1).

Upon further analysis of the FACA recommendations EPA has identified several issues that relate to the monitoring requirements of today's proposed rule. After discussion of these issues which follows, EPA solicits comment on the significance of these issues and how they might best be addressed.

Basing increased monitoring on numbers of water treatment plants per system as currently proposed may result in excessive or insufficient samples to represent DBP occurrence in the distribution system.

Under today's proposal, the required sampling sites increases by the number of plants that feed disinfected water into a system's distribution system. Under this framework some systems, depending upon their size, the number of treatment plants, and the nature of their distribution system, may be required to collect relatively large or small numbers of TTHM and HAA5 samples which may be excessive or insufficient to adequately represent occurrence. Some very large systems have very few large plants while other much smaller systems have many small plants. In EPA's inventory of public water systems, there are some systems with only one plant serving more than 1 million people, whereas other systems serving less than 100,000 people have many water treatment plants, particularly those using ground water .

Determining the number of plants and therefore the number of samples a system must take is a very specific State determination which has not pertained to systems serving less than 10,000 people until recently (this requirement has been in effect for systems serving greater than 10,000 people since implementation of the 1979 TTHM rule). The data on the number of plants estimated in the tables in this section are not from actual State determinations but from the 1997 Community Water Supply Survey (CWSS) (USEPA, 1997b) and are the best estimate currently

available. Uncertainties include: wholesale connections were not included, seasonal sources and sources mixed prior to entering the distribution system may not have been included and aquifer determinations may not have been made. Only 4% of the PWSs were surveyed, and this may not be adequately representative, considering that each water plant determination is a unique determination made by the State. For example, for ground water systems some States require two wells based on their construction standards (for redundancy). For such situations this implies that with no aquifer determination made, the minimum number of WTPs for such ground water systems would be two. EPA is seeking more accurate State information on the number of WTPs per system determined from actual WTP determinations that were made for these rules. With these issues in mind, Table 1 reflects EPA estimates of the numbers of plants per system, by various size categories, for systems using ground water reflected as means, medians, 10^{th} and 90^{th} percentiles, and maximums based on data from the 1997 CWSS (USEPA, 1997b). A plant is defined in the CWSS as a facility that includes at least disinfection and delivers water into the distribution system. Table 1 indicates that for ground water systems serving populations between 10,000 and 50,000 people, at least 10% of the systems had only one treatment plant, 50% (median) had 3 or more treatment plants, and 10% (90^{th} percentile) had 8 or more treatment plants. Under the proposed rule, for each treatment plant that a system has, the system is required to collect the number of samples for each plant that corresponds to those required for the plant's system size category. For example, if a ground water system serves 11,000 people and has three plants it would be required to collect 3 sets of IDSE samples or 24 samples, (3 plants x 2 samples per plant x 4 quarters) unless the State had made a common aquifer

determination for these plants under the Stage 1 rule, or the system qualified for an exclusion by having low DBP levels (see V.E.1.d).

Table 2 reflects EPA estimates of the numbers of plants per system, by various size categories, for systems using surface water or surface water and ground water (mixed systems). Table 2 includes mixed systems because under the proposed Stage 2 rule (as well as under Stage 1) ground water plants in mixed systems are counted as surface water plants for the purpose of defining sampling requirements. For example, in Table 2 under the population size category 50K-100K, one system had 21 treatment plants (indicated by the maximum). This high number of treatment plants is attributed to a system using both surface water and ground water and having a large number of ground water plants contributing water to the distribution system (and without taking into account the same aquifer provision). See Table 2a which reflects the number of plants per system for systems using only surface water.

Noteworthy in Tables 1 and 2 are the wide range of plants per system in the various size categories, particularly among ground water systems, and the wide range of potential monitoring implications. Tables 3 and 4 reflect the numbers of DBP samples that could be required for routine and IDSE monitoring under the proposed rule for a system if the system had the same numbers of plants as the 90^{th} percentile plants per system estimates from the 1997 CWSS. It is important to note the sampling estimates given in Tables 3 and 4 may increase or decrease once actual determinations are made by the State and would not apply to systems having low DBP levels as defined in section V.E.1.d . In its economic analysis for the Stage 2 DBPR, EPA estimates that more than 75% of ground water systems will be exempt from IDSE monitoring because of low DBP levels (USEPA 2001d, Economic Analysis, Appendix F2). While States

can make common aquifer determinations for plants within ground water systems to mixed systems to further reduce monitoring requirements, making such determinations may be difficult because of limited availability of information and resources. Some systems have greater than 100 wells for which the State must make a determination to reduce monitoring. Thus, EPA believes that for some systems, particularly those with many ground water plants, monitoring based on the numbers of water treatment plants per system may lead to excessive DBP monitoring, especially considering that more than 75% have low DBP levels (as previously discussed). On the other hand, for other systems, particularly large surface water systems (see the last row of Table 2), monitoring requirements based on numbers of water treatment plants per system may not result in enough samples to adequately reflect DBP occurrence in the distribution system.

Table 1. Number of Treatment Plants per Systems for Groundwater Systems

(Excluding All Mixed Systems)

(Based on Data from CWSS, USEPA 1997b)

Size Category	No. of Systems in dataset	Number of Treatment Plants per System				
		Mean	10th percentiles	Median	90th percentiles	Maximum
0-499	184	1.2	1	1	2	11
500-4,999	260	1.6	1	1	4	13
5000-9,999	69	2.1	1	1	5	6
10,000-24,999	68	3.4	1	2	8	14
25,000-49,999	27	5.0	1	4	10	18
50,000-99,999	35	6.2	1	4	12	34
100,000-499,999	18	9.9	1	8	30	33
>=500,000	3	8.0	1	-	-	21

Table 2. Number of Treatment Plants per Systems for Surface Water Systems (Including Mixed Systems, i.e., SW+GW)

(Based on Data from CWSS, USEPA 1997b)

Size Category	No. of Systems in dataset	Number of Treatment Plants per System				
		Mean	10th percentiles	Median	90th percentiles	Maximum
0-499	74	1.05	1	1	1	3
500-4,999	118	1.3	1	1	2	6
5000-9,999	49	1.6	1	1	3	5
10,000-24,999	49	1.5	1	1	3	5
25,000-49,999	38	1.8	1	1	3	9
50,000-99,999	65	2.7	1	1	5	21
100,000-499,999	46	3.5	1	2	8	22
>=500,000	19	3.3	1	3	9	10

Table 2a. Number of Treatment Plants per Systems for Surface Water Systems (Excluding All Mixed Systems)

(Based on Data from CWSS, USEPA 1997b)

Size Category	No. of Systems in dataset	Number of Treatment Plants per System				
		Mean	10th percentiles	Median	90th percentiles	Maximum
0-499	67	1.0	1	1	1	2
500-4,999	96	1.1	1	1	1	4
5000-9,999	36	1.2	1	1	2	4
10,000-24,999	35	1.1	1	1	1	2
25,000-49,999	27	1.2	1	1	2	2
50,000-99,999	36	1.7	1	1	3	6
100,000-499,999	27	1.5	1	1	2	3
>=500,000	14	3.1	2	3	4	9

Table 3. Potential Number of IDSE and Routine Samples Required by Groundwater Systems per System

(Excluding all mixed systems)

Size Category	**# plants/system at 90th Percentiles**	***IDSE* Sample's Number per System per Year**	***Stage 2B* Routine Sample's Number per System per Year**	***Stage 1* Routine Sample's Number per System per Year**
0-499	2	8	2 [1]	2
500-4,999	4	16	8 [2]	4
5000-9,999	5	20	10 [2]	5
10,000-24,999	8	64	64 [2]	32
25,000-49,999	10	80	80 [2]	40
50,000-99,999	12	96	96 [2]	48
100,000-499,999	30	240	240 [2]	120
>=500,000	-	-	-	-

[1] If highest TTHM and HAA5 occur at different locations, 2 samples (one for HAA5 analysis and one for TTHM analysis) at different locations must be taken.

[2] If highest TTHM and HAA5 occur at the same location, 4 samples are needed for each system (each with both TTHM and HAA5 analysis).

Table 4. Potential Number of IDSE and Routine Samples Required by Surface Water (Including All Mixed Systems, i.e., SW+GW)

Size Category	# plants/system at 90th Percentiles	*IDSE* Sample Number per System per Year	*Stage 2B* Routine Sample Number per System per Year	*Stage 1* Routine Sample Number per System per Year
0-499	1	4	2 [1]	1
500-4,999	2	16	16 [2]	8
5000-9,999	3	24	24 [2]	12
10,000-24,999	3	144	48 [2]	48
25,000-49,999	3	144	48 [2]	48
50,000-99,999	5	240	80 [2]	80
100,000-499,999	8	384	128 [2]	128
>=500,000	9	432	144	144

[1] If highest TTHM and HAA5 occur at different locations, 2 samples (one for HAA5 analysis and one for TTHM analysis) at different locations must be taken.

[2] If highest TTHM and HAA5 occur at the same location, 4 samples are needed for each system (each with both TTHM and HAA5 analysis).

2) **The proposed sampling requirements for mixed systems (i.e., those receiving disinfected surface water and ground water in their distribution system) may be excessive depending upon the system's characteristics.**

Under the proposal (as under Stage 1 DBPR), systems which receive disinfected water from ground water plants and surface water plants (mixed systems) are required to collect samples for each plant. For each ground water plant that a mixed system has, it must collect the same number of samples as would be required for its surface water plants for that population size. For example, if a system serves more than 10,000 people, has one surface water plant and three ground water plants, regardless of plant size, it would be required to collect the same number of samples as a surface water system with 4 surface water plants or four sets of IDSE samples or 192 IDSE samples (4 plants x 8 samples/plant x 6 sets of samples) and 64 routine samples over four quarters (4 plants x 4 samples/plant x 4 quarters) from Stage 1 to determine monitoring sites for Stage 2B compliance. After Stage 2B monitoring sites are identified, such a system would be required to collect 128 routine samples (4 plants x 8 samples/plant x 4 quarters) over four quarters to determine compliance with Stage 2B. Depending on the total system size and the levels of DBPs contributed from the ground water plants (which could be very low relative to those contributed by the surface water plant), these proposed sampling requirements may be excessive for systems. Table 4 reflects the potential number of samples that could be required for some mixed systems. While the proposal allows States to reduce monitoring requirements for ground water plants in systems with mixed source waters based on common aquifer determinations, such determinations may be difficult to make because of limited

available information and resources, and still adds plants (x 4) for water that may have low DBPs.

3) The proposed monitoring requirements, based on additional samples per water treatment plant, pose unique implementation issues for systems with temporary supplies during the year

Some systems adopt auxiliary supplies during the year to augment water production or to adjust for source water quality changes. For example, a surface water or ground water systems might bring additional wells on line for a few months during the summer time to help meet increased water demand. The FACA did not make any specific recommendations for IDSE or routine compliance monitoring for these types of situations. Under the proposed rule language, additional monitoring would be required according to the number of water treatment plants in a system that were brought on line for those quarters. Therefore, if a system brought another plant on line temporarily, monitoring would have to be conducted for that plant. Issues associated with this approach pertain to the frequency of monitoring to be prescribed and how compliance should be defined with respect to IDSE and routine compliance monitoring.

Approaches for addressing the above issues

EPA solicits comment on the significance of the above monitoring issues and whether the proposed monitoring requirements should be modified. In this regard, EPA is considering two approaches for helping address the above issues. One approach is to keep the existing proposed structure of basing sampling requirements on numbers of plants per system but adding new provisions to address specific issues raised above. Another approach is to base monitoring

requirements on population served in lieu of the numbers of water treatment plants per system. Options within each of these approaches is are discussed following.

Modifications maintaining water treatment plant based monitoring

EPA solicits comment on modifying the proposed monitoring requirements to address the above issues, in part, with provisions such as follows. (1) Should EPA set a limit on the maximum number of IDSE and routine monitoring samples that could be required? Should this limit be different for systems using ground water or surface water or mixed systems? For different system size categories? What rationale should be used to specify maximum sample numbers? (2) Should a provision be included that would allow States to reduce the sampling frequency, beyond those currently proposed (i.e., common aquifer determinations and low DBP levels)? If so, should specific criteria be specified in the rule for systems to meet to qualify for State approval of reduced monitoring? (3) What, if any, criteria should be set by which systems with very large distribution systems but with few plants would be required to conduct additional IDSE or routine monitoring, beyond that currently proposed? (4) For mixed systems, should States be given discretion to reduce routine compliance monitoring samples to a minimum they find to be representative of the systems distribution system but to no less than the number that the plant would be required to do if it were the only plant in the system.

Monitoring requirements based on population served in lieu of the numbers of water treatment plants per system.

In regard to the above issues, EPA is sensitive to wanting to minimize transactional costs to States while providing public health protection. In this regard, EPA has considered another alternative, which would rely on population-based monitoring rather than a plants per system

concept. Under a population based monitoring approach, the total system population served and the source water type would determine the numbers of IDSE and routine samples taken. No monitoring requirements would pertain to numbers of plants that a system had and thus sampling of temporary water supplies would not be an issue. States would not be required to make common aquifer determinations or address temporary sources, or whether plants are combined into a single pipe prior to entering the distribution system. Under a population-based monitoring approach, systems would still be exempt from the IDSE if all their samples under Stage 1 were $\leq$ 40ug/l and 30ug/l for TTHMs and HAA5, respectively.

EPA has developed the following tables for consideration by which both routine compliance monitoring and IDSE monitoring in distribution systems could be based on source water type and total population served to the distribution system. Tables 5 and 6 indicate the numbers of routine and IDSE samples that could be required for Stage 2 B for systems using surface water or surface water and ground water. Tables 7 & 8 indicates numbers (routine and IDSE) of samples that could be required for for systems using only ground water. Specified sampling locations would be similar to those required under the proposed rule.

A population based monitoring approach versus that of the proposed rule would result in some systems taking more samples and other systems taking fewer samples, depending on the numbers of plants a given system had. Tables 9 & 10 indicate the comparative sample burden, on average, that would be associated with the proposed rule versus the population based rule based on the suggested sampling requirements of Table 5-8. EPA solicits comment on the merits of a population based monitoring approach versus the plant based monitoring approach of the proposed rule for the purpose of addressing the issues raised above. Should alternative system

size categories be specified under the suggested population based approach? EPA also solicits comment on what potential issues might be unique for a population based monitoring approach and how they might be addressed.

Table 5 Number of samples required for Stage 2 B* for TTHM/HAA5 (paired samples) for PWSs (including consecutive PWSs) that provide surface water in whole or in part.**

Population	Number of samples
<500	1 TTHM and 1 HAA5 sample per year at different locations and time if the highest TTHM and HAA5 occurred at different locations and/or time **or** 1 TTHM/HAA5 (paired) sample per year if the highest TTHM and HAA5 occurred at the same location and time of year. Must be taken during the peak historical month for DBP concentrations or, if unknown, during month of warmest water temperature.
500 to 4,999	1 TTHM and 1 HAA5 sample per quarter at different locations if the highest TTHM and HAA5 occurred at different locations **or** 1 TTHM/HAA5 (paired) sample per quarter if the highest TTHM and HAA5 occurred at the same location.
5,000 to 9,999	2 paired samples per quarter***
10,000 to 24,999	4 paired samples per quarter***
25,000 to 49,999	6 paired samples per quarter***
50,000 to 99,000	8 paired samples per quarter***
100,000 to 499,999	12 paired samples per quarter***
500,000 to 1,500,000	16 paired samples per quarter.***
>1,500,000	16 paired samples per quarter, plus, for every additional one million persons served above 1,500,000 the system shall take 4 additional paired samples per quarter. One quarterly set.

*See 141.XXXX in this proposed rule to see how the monitoring locations will change for Stage 2 B.
**For systems greater than 5,000 one quarterly set must be taken during the peak historical month for DBP concentrations.
***One quarterly set must be taken during the peak historical month for DBP concentrations, or, if unknown, during month of warmest water temperature.

Table 6 Number of samples required for Stage 2B for TTHM/HAA5 (paired samples) for PWSs (including consecutive PWSs) that provide only ground water.

Population	Number of samples
<500	1 TTHM and 1 HAA5 sample per year at different locations and time if the highest TTHM and HAA5 occurred at different locations and/or time or 1 TTHM/HAA5 (paired) sample per year if the highest TTHM and HAA5 occurred at the same location and time of year. Must be taken during the peak historical month for DBP concentrations, or, if unknown, during month of warmest water temperature. .
500 to 9,999	2 paired samples per year. Must be taken during the peak historical month for DBP concentrations.
10,000 to 100,000	2 paired samples per quarter. One quarterly set must be taken during the peak historical month for DBP concentrations.
100,001 and higher	4 paired samples per quarter. One quarterly set must be taken during the peak historical month for DBP concentrations.

Table 7 Number of samples required for IDSE for PWSs* (including consecutive PWSs) that provide surface water in whole or in part.

Population	Number of samples
<500	2 paired samples every 180 days for one year; one each representative of highest expected TTHM levels and HAA5 levels.
500 to 4,999	2 paired samples approximately every 90 days for one year; one each representative of highest expected TTHM levels and HAA5 levels.
5,000 to 9,999	3 paired samples approximately every 90 days for one year; two representative of highest expected TTHM levels and one representative of highest HAA5 level.
10,000 to 24,999	8 paired samples approximately every 60 days for one year.
25,000 to 49,999	10 paired samples approximately every 60 days for one year.
50,000 to 99,999	12 paired samples approximately every 60 days for one year.
100,000 to 499,999	16 paired samples approximately every 60 days for one year.
500,000 to 1,500,000	20 paired samples approximately every 60 days for one year. For every additional one million persons served above 1,500,000 the system shall take 4 additional paired samples every 60 days.
>1,500,000	20 paired samples approximately every 60 days for one year, plus, for every additional one million persons served above 1,500,000 the system shall take 4 additional paired samples every 60 days.

*Samples must be taken at locations other than Stage 1 DBPR TTHM/HAA5 monitoring locations. For systems serving $10,000 if chlorine is used as a residual: then one sample per 8 samples required must be taken near the distribution system entry point, two per 8 at average residence time and the remaining samples at points representative of the highest expected TTHM or HAA5 concentrations and if chloramine is used as a residual: then two samples per 8 samples required must be taken near the distribution system entry point, two per 8 at average residence time and the remaining samples at points representative of the highest expected TTHM or HAA5 concentrations.

Table 8 Number of samples required for IDSE for PWSs (including consecutive PWSs) that provide only ground water.

Population	Number of samples
<500	2 paired samples every 180 days for one year at locations other than Stage 1 DBPR TTHM/HAA5 monitoring locations; one each representative of highest expected TTHM levels and HAA5 levels.
501 to 9,999	2 paired samples every 90 days for one year at locations other than Stage 1 DBPR TTHM/HAA5 monitoring locations; one each representative of highest expected TTHM levels and HAA5 levels.
10,000 to 100,000	3 paired samples every 90 days for one year at locations other than Stage 1 DBPR TTHM/HAA5 monitoring locations; two representative of highest expected TTHM levels and one representative of highest HAA5 levels.
100,001 and higher	4 paired samples every 90 days for one year at locations other than Stage 1 DBPR TTHM/HAA5 monitoring locations; two each representative of two highest expected TTHM levels and two highest HAA5 levels.

Reduced monitoring would be the number of samples in the proposed language without the reference to "WTPs" except that SW >100,000 could only reduce to 1/4 the number of routine samples required**.**

Table 9. Potential Number of IDSE and Routine Samples Required by Community Surface Water Systems under Plant- or Population-Based Monitoring Approach [1]

Size Category	No. of Systems[2]	Mean No. of Plants per System	No. of IDSE Samples per Year		No. of Routine Samples per Year[3]	
			Plant-Based	Population-Based	Plant-Based	Population-Based
0-499	3398	1.05	14,272	13,592	3,568	3,398
500-4,999	4329	1.3	45,022	34,632	45,022	8,658
5000-9,999	1377	1.6	17,626	16,524	17,626	2,754
10,000-24,999	845	1.5	60,840	40,560	20,280	6,760
25,000-49,999	845	1.8	13,008	50,700	24,336	6,760
50,000-99,999	319	2.7	41,342	22,968	13,781	2,552
100,000-499,999	138	3.5	23,184	13,248	7,728	2,208
>=500,000 [4]	152	3.5	-	-	-	-
Total [5]	**-**	**-**	**275,294**	**192,244**	**132,341**	**33,090**

[1] Plant-based estimates are oversetimates because they do not account for common aquifer determinations, do not account for State waivers.
[2] Based on the data from the SDWIS, 2000.
[3] Worst case, assuming that highest TTHM and HAA5 levels occurr at different locations.
[4] Currently insufficient data, TBD.
[5] Do not include systems > 500k.

Table 10. Potential Number of IDSE and Routine Samples Required by Community Groundwater Systems under Plant- or Population-Based Monitoring Approach [1]

Size Category	No. of Systems [2]	Mean No. of Plants per System	No. of IDSE Samples per Year		No. of Routine Samples per Year [3]	
			Plant-Based	Population-Based	Plant-Based	Population-Based
0-499	17707	1.2	84,994	70,828	21248	17707
500-4,999	8657	1.6	55,405	69,256	27,702	17,314
5000-9,999	1350	2.1	11,340	10,800	5,670	2,700
10,000-24,999	585	3.4	15,912	7,020	7,956	4,680
25,000-49,999	585	5.0	23,400	7,020	23,400	4,680
50,000-99,999	102	6.2	5,059	1,224	5,059	816
100,000-499,999	25	9.9	1,980	400	1,980	400
>=500,000 [4]	27	8.0	-	-	-	-
Total [5]	**-**	**-**	**198,090**	**166,548**	**93,015**	**48,297**

[1] Plant-based estimates are oversetimates because they do not account for common aquifer determinations, do not account for State waivers.
[2] Based on the data from the SDWIS, 2000.
[3] Worst case, assuming that highest TTHM and HAA5 levels occurr at different locations.
[4] Currently insufficient data, TBD.
[5] Do not include systems > 500k.

G. Compliance schedules

1. What is EPA proposing?

Today's proposed rule establishes compliance deadlines for States to adopt and for public water systems to implement the requirements in this rulemaking. Central to the determination of these deadlines is the principle of simultaneous compliance between the Stage 2 DBPR and the LT2ESWTR. Simultaneous compliance ensures continued microbial protection as systems implement changes to decrease DBP levels and minimizes risk-risk tradeoffs.

EPA is proposing a phased MCL strategy and parallel rule compliance at the recommendation of the M-DBP Advisory Committee and in order to comply with SDWA requirements for risk balancing. Subpart H and ground water systems covered by today's proposed rule that serve a population of 10,000 or more must submit the results of their IDSE to their State/primacy agency two years after rule promulgation. In addition, wholesale or consecutive systems that are part of a combined distribution system with at least one system serving $10,000 must meet this schedule. Thus, those systems conducting IDSE monitoring must begin no later than one year after rule promulgation in order to collect and analyze the data and prepare the report, including recommendations for Stage 2B monitoring locations.

Systems must comply with the Stage 2A transitional MCLs for TTHM and HAA5 three years after rule promulgation. Under section1412(b)(10) of the Act, the State may grant up to a two-year extension on a system-by-system basis for systems requiring capital improvements to meet Stage 2A. Systems must comply with Stage 2B six years after rule promulgation. A two-year extension may be granted on a system-by-system basis by the State for systems requiring

capital improvements to simultaneously meet Stage 2B of the Stage 2 DBPR and the LT2ESWTR.

Subpart H and ground water systems covered by today's proposed rule that serve a population of fewer than 10,000 must submit the results of their IDSE to their State/primacy agency four years after rule promulgation. Thus, those systems conducting IDSE monitoring must begin no later than three years after rule promulgation in order to collect and analyze the data and prepare the report, including recommendations for Stage 2B monitoring locations. Systems must comply with Stage 2A transitional MCLs for TTHM/HAA5 three years after rule promulgation. A two-year extension may be granted on a system-by-system basis by the State for systems requiring capital improvements to meet Stage 2A. Small subpart H systems required to do *Cryptosporidium* monitoring under the LT2ESWTR must comply with Stage 2B 8.5 years after rule promulgation. A two-year extension may be granted on a system-by-system basis by the State for systems requiring capital improvements to simultaneously meet Stage 2B and the LT2ESWTR. All other small systems must be in compliance with Stage 2B 7.5 years after rule promulgation (with an additional two-year extension available for systems requiring capital improvements to meet Stage 2B (and LT2ESWTR for subpart H systems)).

This proposed rulemaking provides States two years from promulgation to adopt and implement the requirements of this regulation. States may request an extension of up to two additional years for adoption.

IDSE Schedule Examples

- Wholesale system (pop. 64,000) with three consecutive systems (pops. 21,000; 15,000; 5,000): IDSE report due for all systems two years after promulgation since wholesale system exceeds 10,000

- Wholesale system (pop. 4,000) with three consecutive systems (pops. 21,000; 5,000; 5,000): IDSE report due for all systems two years after promulgation since one consecutive system in combined distribution system exceeds 10,000

- Wholesale system (pop. 4,000) with three consecutive systems (pops. 8,000; 5,000; 5,000): IDSE report due for all systems four years after promulgation since no system in combined distribution system exceeds 10,000 (even though total population exceeds 10,000)

2. How did EPA develop this proposal?

EPA is proposing provisions for parallel rule compliance with the LT2ESWTR to maintain a risk balance between DBP and microbial risks. Simultaneous compliance was mandated by the 1996 SWDA Amendments which require that EPA "minimize the overall risk of adverse health effects by balancing the risk from the contaminant and the risk from other contaminants, the concentrations of which may be affected by the use of a treatment technique or process that would be employed to attain the maximum contaminant level" (Sec. 1412(b)(5)(B)(i)).

If systems were required to comply with the Stage 2 DBPR prior to the LT2ESWTR, systems could lower their disinfectant dose or switch to a less effective disinfectant in an attempt to decrease DBP levels. This practice could leave segments of the population exposed to greater microbial risks. Therefore, simultaneous compliance was a consensus recommendation of the Stage 2 M-DBP Advisory Committee, to ensure that systems would not compromise microbial protection while attempting to meet more stringent DBP requirements.

Under the proposed LT2ESWTR, large and medium subpart H systems are required to monitor their source water for *Cryptosporidium* for two years and based on their findings, consult with their primacy agency regarding required treatment standards. Because of this site-specific risk-based strategy, systems will not be aware of their treatment requirements until three years after rule promulgation. Therefore, EPA is proposing that the three year schedule for compliance should not begin until systems know their site-specific requirements (i.e., three years after rule promulgation). Although this results in compliance timelines for the Stage 2 DBPR and the LT2ESWTR that are somewhat extended, EPA believes that simultaneous compliance will provide the maximum public health benefits. Another proposed provision of the LT2ESWTR is that certain small subpart H systems with low levels of indicators, such as *E. coli*, will not have to monitor for *Cryptosporidium*. However, results from the large and medium system data collection are needed before an assessment of microbial indicators can be completed. Thus, small system *E. coli* monitoring cannot be initiated until large and medium system monitoring has been completed. The compliance timeline for small systems thus lag 1.5 to 2.5 years behind the large and medium system timeline.

EPA is proposing that ground water systems not subject to the LT2ESWTR comply with the Stage 2 DBPR on the same schedule as surface water systems of comparable size. This will ensure consistent State implementation between ground water and surface water systems.

In order to meet the statutory requirement of Section 1412 (b)(10) of the SDWA that a rule become effective three years after promulgation, EPA is proposing a phased MCL. In Stage 2A, all systems must comply with short-term MCLs of 0.120 mg/L TTHM and 0.100 mg/L HAA5 as a LRAA. In addition, all systems must continue to comply with the Stage 1 DBPR

MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as a running annual average (RAA). In Stage 2B, systems must comply with long-term MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as a locational running annual average (LRAA) based on new sampling sites identified under the IDSE. EPA believes that this phased MCL strategy is an incremental approach to shaving DBP peak occurrence levels that ensures simultaneous compliance. In addition, it provides systems with the opportunity to gradually develop their approach for compliance with an LRAA standard.

3. Request for comments

EPA requests comments on today's proposed compliance schedules. Specifically:

- Should monitoring for ground water systems serving $10,000 be delayed to be on the same schedule as small (<10,000) systems as was done in the Stage 1 DBPR in order to allow States to gain primacy before the IDSE?

- Should compliance with Stage 2B for small (<10,000) consecutive systems that submit an IDSE report two years after promulgation be delayed until the compliance date for small systems (7.5 or 8.5 years after promulgation) in order to allow the consecutive system time to evaluate the effect of treatment changes by the large systems in the combined distribution system?

H. Public notice requirements

1. What is EPA proposing?

A public water system that fails to comply with any applicable requirement of the SDWA (as defined in 1414 (i)) is subject to an enforcement action under the provisions of section 1414. Applicable requirements include, but are not limited to, MCLs, treatment techniques, monitoring and reporting. These regulatory requirements are set out in 40 CFR l41.

In addition, SDWA Section 1414(c) requires PWSs to provide notice to their customers for certain violations or in other circumstances. EPA's public notification rule was published on May 4, 2000 (65 FR 25982), and is codified at 40 CFR 141.201-141.210 (Subpart Q). Today EPA is proposing to modify the existing TTHM and HAA5 health effects language that is required in most public notices under Subpart Q to include information about the possible reproductive or fetal development effects that may be associated with high levels of these DBPs.

For TTHM, EPA is proposing to change the language in 40 CFR 141 Subpart Q, Appendix B to read:

> "Some people who drink water containing trihalomethanes in excess of the MCL over many years may experience problems with their liver, kidneys, or central nervous system, and may have an increased risk of getting cancer. Some studies have also indicated a possible link between reproductive or fetal development problems and drinking water with high levels of TTHM."

For HAA5, EPA is proposing to change the language to read:

> "Some people who drink water containing halocetic acids in excess of the MCL over many years may experience problems with their liver and kidneys, and may have an

increased risk of getting cancer. Some studies have also indicated a possible link between reproductive or fetal development problems and drinking water with high levels of HAA5."

2. Request for comments

EPA requests comment on the proposed public notification requirements.

I. Variances and exemptions

Variances may be granted in accordance with sections 1415(a) and 1415(e) of the SDWA and EPA's regulations. Exemptions may be granted in accordance with section 1416 of the SDWA and EPA's regulations.

1. Variances

The SDWA provides for two types of variances - general variances and small system variances. Under section 1415(a)(1)(A) of the SDWA, a State which has primary enforcement responsibility (primacy), or EPA as the primacy agency, may grant variances from MCLs to those public water systems of any size that cannot comply with the MCLs because of characteristics of the water sources. The primacy agency may grant general variances to a system on the condition that the system install the best available technology, treatment techniques, or other means, that EPA finds available and promulgates with the NPDWR for the contaminant at issue and provided that alternative sources of water are not reasonably available to the system. At the time this type of variance is granted, the State must prescribe a compliance schedule and may require the system to implement additional control measures. Furthermore, before EPA or the State may grant a general variance, it must find that the variance will not result in an unreasonable risk to health to the public served by the public water system.

Under section 1413(a)(4), primacy States that choose to issue general variances must do so under conditions, and in a manner, that are no less stringent than section 1415. Of course, a State may adopt standards that are more stringent than the EPA standards. EPA specifies BATs for general variance purposes. EPA may identify as BAT different treatments under section 1415 for variances other than the BAT under section 1412 for MCLs. EPA's section 1415 BAT findings may vary depending on a number of factors, including the number of persons served by the public water system, physical conditions related to engineering feasibility, and the costs of compliance with MCLs. In this proposed rule, EPA is specifying different BAT for variances under section 1415(a) than those in the Stage 1 DBPR. There are also treatment technique variances under 1415 (a)(3).

Section 1415(e) authorizes the primacy Agency (EPA or the State) to issue variances to small public water systems (those serving fewer than 10,000 persons) where the system cannot afford to comply with an MCL and where the primacy agency determines that the terms of the variances ensure adequate protection of public health (63 FR 1943-57; USEPA, 1998d). These variances also may only be granted where EPA has identified a variance technology under Section 1412(b)(15) for the contaminant, system size and source water quality in question.

The cost assessment for the feasibility determinations used in setting NPDWRshave historically been based upon impacts to regional and large metropolitan water systems serving populations greater than 50,000 people. Since large systems served as the basis for the feasibility determinations, the technical and/or cost considerations associated with these technologies often were not applicable to small water systems. While EPA will continue to use feasibility for large systems in setting NPDWRs, the 1996 Amendments to the SDWA

specifically require EPA to make small system technology assessments for both existing and future regulations.

The 1996 Amendments to the SDWA identify three categories of small public water systems that need to be addressed: (1) those serving a population of 3301 - 10,000; (2) those serving a population of 500 - 3300; and (3) those serving a population of 25 - 499. The SDWA requires EPA to make determinations of available compliance technologies and, if needed, variance technologies for each size category. A compliance technology is a technology that is affordable and that achieves compliance with the MCL and/or treatment technique. Compliance technologies can include point-of-entry or point-of-use treatment units. Variance technologies are only specified for those system size/source water quality combinations for which there are no listed compliance technologies.

EPA has completed an analysis of the affordability of DBP control technologies for each of the three size categories included above. Based on this analysis, multiple affordable compliance technologies were found for each of the three system sizes (USEPA, 1998k and USEPA, 1998l) and therefore variance technologies were not identified for any of the three size categories. The analysis was consistent with the methodology used in the document "National-Level Affordability Criteria Under the 1996 Amendments to the Safe Drinking Water Act" (USEPA, 1998i) and the "Variance Technology Findings for Contaminants Regulated Before 1996" (USEPA, 1998j). Therefore, section 1415(e) variances will not be available for this rule.

2. Exemptions

Under section 1416(a), EPA or a State may exempt a public water system from any requirements related to an MCL or treatment technique of an NPDWR, if it finds that (1) due to

compelling factors (which may include economic factors such as qualification of the PWS as serving a disadvantaged community), the PWS is unable to comply with the requirement or implement measure to develop an alternative source of water supply; (2) the exemption will not result in an unreasonable risk to health; (3) the PWS was in operation on the effective date of the NPDWR, or for a system that was not in operation by that date, only if no reasonable alternative source of drinking water is available to the new system; and (4) management or restructuring changes (or both) cannot reasonably result in compliance with the Act or improve the quality of drinking water.

If EPA or the State grants an exemption to a public water system, it must at the same time prescribe a schedule for compliance (including increments of progress or measures to develop an alternative source of water supply) and implementation of appropriate control measures that the State requires the system to meet while the exemption is in effect. Under section 1416(b)(2)(A),the schedule shall require compliance as expeditiously as practicable (to be determined by the State), but no later than three years after the compliance date required by the regulations. For public water systems which do not serve more than a population of 3,300 and which need financial assistance for the necessary improvements, EPA or the State may renew an exemption for one or more additional two-year periods, but not to exceed a total of six years, if the system establishes that it is taking all practicable steps to meet the requirements above.

A public water system shall not be granted an exemption unless it can establish that: (1) the system cannot meet the standard without capital improvements that cannot be completed prior to the date established pursuant to section 1412(b)(10); **OR** (2) in the case of a system that needs financial assistance for the necessary implementation, the system has entered into an

agreement to obtain financial assistance pursuant to section 1452 or any other Federal or state program; **OR** (3) the system has entered into an enforceable agreement to become part of a regional public water system.

J. Requirements for systems to use qualified operators

EPA believes that systems that must make treatment changes to comply with requirements to reduce microbiological risks and risks from disinfectants and disinfection byproducts should be operated by personnel who are qualified to recognize and react to problems. Therefore, the Agency, in the Stage 1 DBPR, required that all systems regulated under the Stage 1 DBPR be operated by an individual who meets State specified qualifications, which may differ based on system size and type. Subpart H systems already were required to be operated by qualified operators under the SWTR (40 CFR 141.70). The Stage 1 DBPR added requirements for disinfected systems to be operated by qualified personnel who meet the requirements specified by the State. The rule also required that States maintain a register of qualified operators (40 CFR 141.30(c)). While the proposed Stage 2 DPBR requirements do not supercede or modify the requirement that disinfected systems be operated by qualified personnel, the Agency would like to emphasize the important role that qualified operators play in delivering safe drinking water to the public. EPA encourages States which do not already have operator certification programs in effect to develop such programs. States should also review and modify, as required, their qualification standards to take into account new technologies (e.g., ultraviolet (UV) disinfection) and new compliance requirements (including simultaneous compliance).

K. System reporting and recordkeeping requirements

1. Confirmation of applicable existing requirements

Today's proposed Stage 2 DBPR, consistent with the current system reporting regulations under 40 CFR 141.131, requires public water systems to report monitoring data to States within ten days after the end of the compliance period. In addition, systems are required to submit the data required in §141.134. These data are required to be submitted quarterly for any monitoring conducted quarterly or more frequently, and within ten days of the end of the monitoring period for less frequent monitoring. Systems that are required to do extra monitoring because of the disinfectant used have additional reporting requirements. This applies to systems that use chlorine dioxide (who must report chlorine dioxide and chlorite results) and ozone (who must report bromate results).

Summary of Additional Reporting Requirements

The requirements in the proposed Stage 2 DBPR apply to all community water systems and non-transient non-community water systems that add a disinfectant or deliver water that has been disinfected.

EPA proposes that two years after rule promulgation, systems serving 10,000 or more people be required to report to their State, the results of their IDSE which consists of either monitoring data or other system-specific data that will provide equivalent or better information on site selection, unless the State has waived this requirement for systems serving fewer than 500. Systems are also required to report to the State recommended long-term (Stage 2B) compliance monitoring sites as part of the IDSE report.

Beginning three years after rule promulgation (five years for systems granted an extension), systems must report compliance with Stage 2A MCLs based on a LRAA (0.120 mg/L TTHM and 0.100 mg/HAA5), as well as continue to report compliance with 0.080 mg/L TTHM and 0.060 mg/L HAA5 as a RAA. Systems must report compliance with the long-term Stage 2B TTHM and HAA5 MCLs (0.080 mg/L TTHM and 0.060 mg/L HAA5 as a LRAA) according to the compliance schedules outlined in section V.H of today's proposal. Reporting for DBP monitoring, as described above, would remain consistent with current public water system reporting requirements (§ 141.31 and § 141.134); systems would be required to report each LRAA and each individual monitoring result. Systems would also be required to consult with the State about each peak excursion event no later than the next sanitary survey for the system.

2. Request for Comment

EPA requests comment on all system reporting and recordkeeping requirements.

L. Analytical method requirements

1. What is EPA proposing today?

The Stage 2 DBPR proposed today does not add any new disinfectants or disinfection byproducts to the list of contaminants currently covered by MRDLs or MCLs. However, additional methods have become available since the analytical methods in the Stage 1 DBPR were promulgated (USEPA, 1998c). EPA is proposing to add one method for chlorine dioxide, one method for HAA5 which can also be used to analyze for the regulated contaminant dalapon, three methods for bromate, chlorite, and bromide, one method for bromate only, one method for THMs which can also be used to analyze for volatile organic compounds (VOCs), and one method for TOC and specific ultraviolet absorbance (SUVA).

Several of the methods that were promulgated with the Stage 1 DBPR have been included in publications that were issued after December 1998. EPA is proposing to allow the use of the most recently published versions of three methods for determining free, combined, and total chlorine residuals, two methods for total chlorine only, one method for free chlorine only, one method for chlorite and chlorine dioxide, one method for chlorine dioxide only, one method for bromate, chlorite, and bromide, one method for HAA5, three methods for TOC and disolved organic carbon (DOC), and one method for UV 254.

EPA is also proposing to approve the 21st edition of *Standard Methods for the Examination of Water and Waste Water* for methods cited in this proposed rule that do not substantively change between the 20th and 21st editions.

Analytical methods that are proposed in today's rule are summarized in Table V.2.

Table V.2. Analytical methods proposed for approval in today's rule

Analyte	EPA Method	Standard Method[1]	Other
Chlorine (*free, combined, total*)		4500-Cl D	
		4500-Cl F	
		4500-Cl G	
(*total*)		4500-Cl E	
		4500-Cl I	
(*free*)		4500-Cl H	
Chlorine Dioxide	XXX.0	4500-ClO_2 D	
		4500-ClO_2 E	
TTHM	524.3		

Analyte	EPA Method	Standard Method[1]	Other
VOCs			
Benzene	524.3		
Carbon tetrachloride	524.3		
Chlorobenzene	524.3		
1,2-Dichlorobenzene	524.3		
1,4-Dichlorobenzene	524.3		
1,2-Dichloroethane	524.3		
cis-Dichloroethylene	524.3		
trans-Dichloroethylene	524.3		
Dichloromethane	524.3		
1,2-Dichloropropane	524.3		
Ethylbenzene	524.3		
Styrene	524.3		
Tetrachloroethylene	524.3		
1,1,1-Trichloroethane	524.3		
Trichloroethylene	524.3		
Toluene	524.3		
1,2,4-Trichlorobenzene	524.3		
1,1-Dichloroethylene	524.3		
1,1,2-Trichloroethane	524.3		
Vinyl chloride	524.3		
Xylenes (total)	524.3		
HAA5	552.1[2]	6251 B[2]	
	552.3		
Dalapon	552.3		
Bromate	300.1		ASTM D 6581-00
	317.1		
	321.8		
	325.0		

Analyte	EPA Method	Standard Method[1]	Other
Chlorite (*monthly or daily*)	300.1 317.1 325.0		ASTM D 6581-00
(*daily*)		4500-ClO_2 E	
TOC/DOC	415.3	5310 B 5310 C 5310 D	
UV_{254}	415.3	5910 B	
SUVA	415.3		
Bromide	300.1 317.1 325.0		ASTM D 6581-00

[1] EPA is proposing to cite the 20th and 21st editions of *Standard Methods for the Examination of Water and Waste Water* in addition to the currently cited 19th editions.
[2] EPA is proposing to change the sample holding time to 14 days.

2. How was this proposal developed?

EPA evaluated the performance of the new methods for their applicability to compliance monitoring. The primary purpose of this evaluation was to determine if the new methods provide data of comparable or better quality than the methods that are currently approved. This evaluation is discussed below.

EPA also reviewed the new publications of methods and determined that these newer editions did not change the individual methods. EPA proposes to allow the use of the most recently published version of the methods. This is discussed below.

a. Disinfectants

Today's rule proposes to update the methods for determining disinfectant residuals to include the most recent versions published by the Standard Methods Committee. The Stage 1 DBPR approved eight methods for determining disinfection residuals from the 19th edition of *Standard Methods*. All of these methods are unchanged in the 20th edition, so EPA proposes to cite the 20th edition for these analyses in addition to the 19th edition. EPA believes both editions should be cited to allow flexibility for the water systems performing these analyses. Withdrawal of the older edition would require all systems to purchase the newer edition, which could place an unnecessary burden on systems that use the reference for only a few methods.

EPA also recognizes that the 21st edition of *Standard Methods* will be issued prior to this rule becoming final. EPA proposes that the final rule also cite the 21st edition, if there are no substantive changes in these methods between the 20th and 21st editions. EPA requests comments as to the appropriateness of including the 21st edition in the final rule, if there are no

substantive changes in the disinfectant residual methods between the edition now in print (i.e., 20th edition) and the one that will be issued prior to the final rule (i.e., 21st edition).

EPA is proposing to add a new method for the measurement of chlorine dioxide residuals. EPA XXX.0 is a spectrophotmetric method in which the chromophore lissamine green B is added to both the sample and a blank. Chlorine dioxide reacts with the chromophore to reduce the absorbance of the sample solution. The difference in absorbance between the sample and the blank is proportional to the chlorine dioxide concentration in the sample.

{Add discussion on the sensitivity, accuracy, and precision of new method when development work is completed.}

b. Disinfection byproducts

Today's rule proposes to update the version of *Standard Methods* cited for HAA5 determinations, to correct a sample holding time discrepancy in the HAA5 Standard Method and EPA Method 552.1 for HAA5, to update the citation for EPA Method 300.1 for chlorite and bromate, to add one new method for HAA5 which can also be used in compliance monitoring for the synthetic organic chemical dalapon, to add one new method for TTHM which can also be used in compliance monitoring for VOCs, to add three new methods for chlorite and bromate, and to add one new method for bromate.

Standard Method 6251 B for haloacetic acids in the 19th edition of *Standard Methods* was approved under the Stage 1 DBPR for HAA5 analyses. This method is unchanged in the 20th edition, so EPA proposes to cite the 20th edition for this analysis in addition to the 19th edition. EPA also proposes that the 21st edition be cited in the final rule, if there are no substantive changes between the 20th and 21st editions for Standard Method 6251 B. EPA requests

comments as to the appropriateness of including the 21st edition in the final rule, if there are no substantive changes in Standard Method 6251 B between the edition now in print (i.e., 20th edition) and the one that will be issued prior to the final rule (i.e., 21st edition).

The analytical methods approved for HAA5 compliance monitoring (USEPA 552.1, EPA 552.2, and Standard Method 6251 B) all specify the use of ammonium chloride to eliminate the free chlorine residual in samples and they require samples be iced/refrigerated after collection. Even though the sampling parameters agree in the three methods, the methods specify different sample holding times (time between sample collection and extraction). The EPA methods allow at least 14 days while Standard Method 6251 B specifies that samples must be extracted within nine days of sample collection. The holding time for the Standard Method is based on data which indicated an increase in DCAA concentration to slightly greater than 120% of the initial concentration after the sample was stored for 14 days (Krasner et al., 1989). All other HAA5 compounds were well within the 80-120% criteria set by the researchers. The decision was made to use a conservative approach to be sure that the concentrations of all HAAs were stable, and nine days was the closest data point to the 14 day-data point in question. Subsequent to Krasner's study, EPA conducted additional sample holding time studies as part of the EPA methods development process. EPA has published data to support the 14-day sample holding time for the HAA5 compounds (Pawlecki-Vonderheide et al., 1997; need reference for EPA Method 552.3 holding time data that is still under development). Since there is no technical reason for the holding times to be different between the HAA5 methods addressed in this rule, EPA proposes to allow a 14-day sample holding time for samples being analyzed by Standard

Method 6251 B. This would provide consistency across methods and it would simplify sampling considerations for water systems.

EPA Method 552.1 specifies a 28-day holding time for HAA samples. This was based on studies conducted on fortified reagent water samples rather than drinking water samples. EPA believes that some samples may not be stable for 28 days, so today's rule proposes reducing the holding time to 14 days when this method is used. Reducing the allowable sample holding time in EPA Method 552.1 to 14 days would better ensure sample stability. During the ICR, EPA only allowed the 14-day sample holding time for all HAA samples (regardless of the method used to analyze the samples), so laboratories and water systems have demonstrated their capability to implement this method change.

EPA believes that by standardizing the holding times allowed in the various HAA5 methods, the burden for laboratories and water systems will be reduced. Sampling considerations will be simplified, because all HAA5 samples will be collected and stored the same way. EPA requests comments as to whether standardizing the sample holding times for the HAA5 methods is appropriate.

EPA is proposing to add a new method (USEPA Method 552.3) for HAA5 which provides comparable sensitivity, accuracy, and precision to the previously approved methods. The new method has the added benefit of allowing laboratories to more easily measure three additional haloacetic acids (bromodichloroacetic acid, chlorodibromoacetic acid, and tribromoacetic acid) at the same time the HAA5 compounds are being measured. Even though these compounds are not required to be determined for compliance monitoring purposes, EPA believes that many public water systems would like to obtain data on these compounds. Water

systems that are making changes in their treatment processes may want to collect data on the formation of the nine HAAs determined by this method, because some treatment changes may cause the speciation of HAAs to shift to the more brominated compounds. Information on these changes would provide the water systems with a better understanding of their water quality in relation to DBPs. Of the currently approved methods for HAA5, only EPA Method 552.2 provides method performance data for these additional compounds. Under carefully controlled conditions, particularly the methylation reaction time and temperature, the method can be successfully used to measure the additional HAAs. However, EPA believes that analyses for these additional HAAs can be accomplished more easily without compromising the quality of data for the HAA5 compounds by using EPA Method 552.3.

EPA Method 552.3 for HAA5, four other haloacetic acids, and the regulated contaminant dalapon allows two extraction options. The first option involves an acidic extraction with methyl tertiary butyl ether (MTBE) which is the same solvent used in the currently approved HAA5 methods. The analytes (HAA5, other HAAs, and dalapon) are then converted to their methyl esters by the addition of acidic methanol to the extract followed by heating. The amount of acidic methanol which is added to the extract is doubled in the new method resulting in increased methylation efficiency for some of the analytes. The increased methylation efficiency is significant for the additional HAAs and thus provides greater sensitivity, precision, and accuracy for them when compared to EPA Method 552.2. The acidic extract is neutralized by a back-extraction with a saturated solution of sodium bicarbonate and the target analytes are identified and measured by gas chromatography using electron capture detection (GC/ECD).

The second option in the new EPA Method 552.3 involves an acidic extraction with tertiary amyl methyl ether (tAME). The use of tAME instead of MTBE as the extraction solvent results in a higher percentage of the analytes being transferred from the water sample into the extraction solvent when compared to EPA Method 552.2. This increased extraction efficiency provides significant increases in sensitivity, precision, and accuracy for the additional HAAs. The HAAs are then converted to their methyl esters by the addition of acidic methanol to the extract followed by heating. The acidic extract is neutralized by a back-extraction with a saturated solution of sodium bicarbonate and the target analytes are identified and measured by gas chromatography using electron capture detection (GC/ECD).

The performance of EPA Method 552.3 is comparable to the currently approved methods for determining the HAA5 analytes. A comparison of the performance of EPA Method 552.3 to the currently approved HAA5 methods is shown in the following table. The data are taken from the individual methods, so the precision, accuracy, and detection data were not generated using the same samples. The data also reflect performance within a single laboratory for each method.

QC Parameter	MCAA	DCAA	TCAA	MBAA	DBAA
Precision (Max %RSD in fortified drinking water samples)[1]					
EPA 552.1	15	14	28	11	7
EPA 552.2	13	6	15	6	5
EPA 552.3 (MTBE option)	5	3	3	4	3
EPA 552.3 (tAME option)					
SM 6251 B	8	7	6	8	7
Accuracy (Range of % Recoveries in drinking water samples)[2]					
EPA 552.1	76-100	75-126	56-106	86-97	94-103
EPA 552.2	84-97	96-105	62-82	86-100	72-112
EPA 552.3 (MTBE option)	101-123	92-97	92-100	92-96	98-100
EPA 552.3 (tAME option)					
SM 6251 B	99-103	96-103	100-103	97-101	102
Detection Level (Fg/L)[3]					
EPA 552.1	0.21	0.45	0.07	0.24	0.09
EPA 552.2	0.27	0.24	0.08	0.20	0.07
EPA 552.3 (MTBE option)	0.08	0.05	0.02	0.03	0.03
EPA 552.3 (tAME option)					
SM 6251 B	0.08	0.05	0.05	0.09	0.06

[1]The highest relative standard deviation (%RSD) for replicate analyses of fortified drinking water samples as shown in each method.
[2]The range of recoveries reported for replicate analyses of fortified drinking water samples as shown in each method.
[3]The detection level as determined by analyzing seven or more replicates of reagent water that is fortified with low concentrations of the haloacetic acids. The standard deviation of the mean concentration for each analyte is calculated and multiplied by the student's t-value at 99% confidence and n-1 degrees of freedom (3.143 for 7 replicates).

Two of the currently approved HAA5 methods (USEPA Methods 552.1 and 552.2) are also approved for analyses of water samples for dalapon, a synthetic organic chemical. The new HAA5 method can also be used to determine dalapon in drinking water. As shown in the following table, both solvent options in EPA Method 552.3 provide comparable or better method performance than the approved methods.

Dalapon Performance Characteristic	EPA 552.1	EPA 552.2	EPA 552.3	
			MTBE	tAME
Precision[1] (%RSD)	14	11	2	
Accuracy[2] (% Recovery)	88-102	86-100	101-113	
Detection Level[3] (Fg/L)	0.32	0.12	0.05	

[1]The highest relative standard deviation (%RSD) for replicate analyses of fortified drinking water samples as shown in each method.
[2]The range of recoveries reported for replicate analyses of fortified drinking water samples as shown in each method.
[3]The detection level as determined by analyzing seven or more replicates of reagent water that is fortified with low concentrations of dalapon. The standard deviation of the mean dalapon concentration is calculated and multiplied by the student's t-value at 99% confidence and n-1 degrees of freedom (3.143 for 7 replicates).

EPA is proposing to approve EPA Method 552.3 for dalapon (§141.24(e)(1)) in addition to HAA5 even though dalapon is not a contaminant that is addressed in this proposed rule. EPA believes that extending approval to all the regulated contaminants covered by the method provides more flexibility to laboratories. It allows the laboratories the option of reducing the number of methods that they need to keep in operation for their clients, because the new method can be used for dalapon and HAA5 compliance monitoring samples and for determining the additional HAAs for non-regulatory purposes. This approach is more cost effective for laboratories, because switching between methods results in increased analyst and instrument time. EPA is not proposing to withdraw the other dalapon methods, because that would reduce flexibility for the laboratories and place an unnecessary burden on laboratories who do not need to use EPA Method 552.3.

EPA Method 300.1 for chlorite and bromate is now included in an EPA methods manual that was published August 2000. The manual titled "Methods for the Determination of Organic and Inorganic Compounds in Drinking Water" is a compilation of methods developed by EPA for drinking water analyses. EPA Method 300.1 was previously only available as an individual method. EPA proposes to update the chlorite and bromate citation for this method to the August 2000 methods manual so that the users are directed to the correct source of the method.

The first method that EPA is proposing to add for chlorite and bromate compliance monitoring is ASTM Method D 6581-00. This method is equivalent to EPA Method 300.1 (Hautman et al., 2000). The interlaboratory study data demonstrate good precision and low bias for both analytes. Because this method uses the same technology as EPA Method 300.1, it has

the same sensitivity. The instrumentation for this method is widely available in laboratories throughout the country.

The second method that EPA is proposing to add for chlorite and bromate is EPA Method 317.1. This method is an extension of the currently approved EPA Method 300.1 for chlorite and bromate. It allows for determination of chlorite and bromate using the EPA Method 300.1 technology, but it adds a post-column reactor which provides a more sensitive and specific analysis for bromate than is obtained using EPA Method 300.1. As with EPA Method 300.1, the anions are separated by ion chromatography and detected using a conductivity detector. After the sample passes through the conductivity detector, it enters a post-column reactor chamber in which *o*-dianisidine dihydrochloride (ODA) is added to the sample. This compound forms a chromophore with the bromate that is present in the sample and the chromophore concentration is determined using a ultraviolet/visible (UV/VIS) absorbance detector. There are several advantages of this method:

1) Very few ions react with ODA to form compounds that are detected by the UV/VIS detector. This makes the method less subject to interferences for bromate.

2) The UV/VIS detector is very sensitive to the chromophore, so lower concentrations of bromate can be detected and quantitated. (Bromate concentrations can be reliably quantitated as low as 1 Fg/L using this method versus 5 Fg/L for EPA Method 300.1.)

3) Since the front part of the analysis is the same as EPA Method 300.1, both chlorite and bromate can be determined at the same time.

The first version of this method, EPA Method 317.0 has been evaluated in a multiple laboratory study (Wagner et al., 2000). The results from the study indicate high precision and

very low bias in data generated using this method. The interlaboratory precision for chlorite and bromate using the conductivity detector and bromate using the UV/VIS detector are 4.2%, 12%, and 9.6% relative standard deviation (RSD), respectively. The interlaboratory bias for chlorite and bromate using the conductivity detector and bromate using the UV/VIS detector are -0.98%, 0.35%, and 4.8%, respectively. The average detection levels for chlorite and bromate using the conductivity detector and bromate using the UV/VIS detector are 1.62, 2.17, and 0.24 Fg/L, respectively.

Subsequent to the interlaboratory study of EPA Method 317.0, a problem with ODA was discovered. The purity of the reagent can vary from lot to lot purchased from the suppliers and this affects the performance of the method. EPA has evaluated the method performance using ODA obtained from several commercial sources and from different lots from the same supplier. Based on that new information, EPA revised Method 317.0 to document how to detect and correct problems that can result from a contaminated ODA supply. The revised method is designated EPA Method 317.1 and this is the version that is being proposed today. The performance of the revised method is identical to the original version.

The third method that EPA is proposing to add for chlorite and bromate is EPA Method 325.0. This method is based on the procedure reported by Salhi and von Gunten (1999) and uses an approach that is similar to EPA Method 317.1. The method involves the separation of the oxyhalide anions (chlorite and bromate) following the scheme outlined in EPA Methods 300.1 and 317.1. The eluent stream exiting the conductivity detector is mixed with a postcolumn reagent consisting of an acidic solution of potassium iodide with a catalytic concentration of

molydenum (IV). Bromate reacts with the iodide to form triiodide which is measured by its UV absorption at 352 nm.

EPA Method 325.0 has similar sensitivity for bromate compared to EPA Method 317.1 and it allows the simultaneous determination of chlorite. Single laboratory determinations of precision and accuracy of analyses for bromate in fortified drinking water samples show XX% RSD and XX% recovery. The detection level is 0.17 Fg/L as determined by analyzing seven or more replicates of reagent water that is fortified with low concentrations of bromate. The standard deviation of the mean bromate concentration is calculated and multiplied by the student's t-value at 99% confidence and n-1 degrees of freedom (3.143 for 7 replicates). {Method performance data will be added in a later version. Second lab data validation will also be added when it becomes available.}

EPA believes both EPA Methods 317.1 and 325.0 should be approved as additional methods for chlorite and bromate compliance monitoring. (USEPA Method 300.1, 317.1, and 325.0 are equivalent for chlorite measurements.) Since EPA Methods 317.1 and 325.0 are more sensitive than EPA Method 300.1 for bromate, EPA anticipates that water systems will prefer to have their bromate samples analyzed by one of these new methods, because they provide higher quality data than the currently approved method when bromate concentrations are below the MCL of 10 Fg/L. Only a few laboratories are currently performing analyses using the post column reactor technology included in these methods, but the number is increasing as more laboratories become aware of the advantages.

The first method that EPA is proposing to add specifically for bromate compliance monitoring is EPA Method 321.8. It involves an ion chromatograph coupled to an inductively

coupled plasma mass spectrometer (ICP-MS). The ion chromatograph separates bromate from other ions present in the sample and then bromate is detected and quantitated by the ICP-MS. Mass 79 is used for quantitation while mass 81 provides isotope ratio information which can be used to screen for potential polyatomic interferences. The advantage of this method is that it is very specific and sensitive to bromate. The single laboratory detection limit presented in the method is 0.3 Fg/L. The average accuracy reported in the method for laboratory fortified blanks is 99.8% recovery with a three sigma control limit of 10.2%. Average accuracy and precision in fortified drinking water samples are reported as 97.8% recovery and 2.9% relative standard deviation, respectively.

During the ICR, several samples were analyzed by this method in addition to the selective anion concentration (SAC) method used by EPA for the low-level bromate analyses. EPA Method 321.8 provided comparable data to that generated by the SAC method. {ref-internal report summarizing the data}

EPA Method 321.8 has undergone second laboratory validation (Day et al., 2001) and the results indicate the method can be successfully performed in non-EPA laboratories. The calculated detection limit determined by the second laboratory is 0.4 Fg/L. The average accuracy achieved for laboratory fortified blanks at 5 Fg/L is 93% recovery with a relative standard deviation of 8.9%. Average accuracy and precision in fortified drinking water samples are reported as 101% recovery and 9% relative standard deviation, respectively.

The IC-ICP/MS instrumentation used in EPA Method 321.8 is a new technology in the laboratory community. Even though the technology is not yet widely used, EPA believes that approving this new method will provide laboratories with the flexibility to adopt the new

technology if they have additional applications for it. The instrumentation is especially promising in the area of trace metal speciation. Laboratories that are perfoming those type of analyses would find it very useful to also be able to perform bromate compliance monitoring analyses by EPA Method 321.8. EPA believes that advances in analytical technology should be encouraged when they provide additional options for obtaining accurate and precise data for compliance monitoring.

EPA is proposing to add a sample collection requirement to EPA Method 321.8. The current method does not address the potential for changes in bromate concentrations after the sample is collected as a result of reactions with hypobromous acid/hypobromite ion. Hypobromous acid/hypobromite ion are intermediates formed as byproducts of the reaction of either ozone or hypochlorous acid/hypochlorite ion with bromide ion. If not removed from the sample matrix, further reactions may form bromate ion. The reactions can be prevented by adding 50 mg of ethylenediamine (EDA)/L of sample. This is the preservation technique specified in the other methods both approved and proposed for bromate compliance analyses. The fortified drinking water samples analyzed in the second laboratory validation study of EPA Method 321.8 (Day et al., 2001) were preserved with EDA. EPA believes that adding this sample preservation requirement to EPA Method 321.8 will ensure sample integrity. It will also simplify the sampling protocols that water systems must follow, because all sampling for bromate, regardless of the method employed to analyze the sample, will require the same sample preservation technique.

Today's rule proposes reduced bromate monitoring for water systems who can demonstrate their finished water bromate concentration is $\leq$0.005 mg/L as a running annual

average. In order to qualify for this reduced monitoring, the samples must be analyzed for bromate using either EPA Method 317.1 (UV/VIS detector), EPA Method 325.0, or EPA Method 321.8. These are the only available methods with the sensitivity to reliably measure bromate concentrations <0.005 mg/L. Laboratories that analyze these samples must be able to provide quantitative data for bromate concentrations as low as 0.001 mg/L using either EPA Method 317.1, EPA Method 325.0, or EPA Method 321.8.

Since EPA Methods 317.1, 325.0 and 321.8 offer significantly greater sensitivity for bromate analyses, EPA considered whether these should be the only methods approved for bromate compliance monitoring. However, the new methods using post column reactions with UV/VIS detection (USEPA Methods 317.1 and 325.0) or IC-ICP/MS (USEPA Method 321.8) require greater analyst skill than is necessary for the standard IC methodology (USEPA Method 300.1 and ASTM Method D 6581-00). They also require instrumentation that may not be currenly owned by many laboratories who perform bromate analyses. As a result of these factors and because the standard IC methods are adequate for determining compliance with the bromate MCL that was promulgated as part of the Stage 1 DBPR, EPA decided not to propose withdrawal of the currently approved method (USEPA Method 300.1). In addition, EPA decided to propose ASTM Method D 6581-00, because it is equivalent to EPA Method 300.1. EPA strongly encourages laboratories to expand their services by adding the capability to perform analyses using one of the more sensitive methods for bromate. EPA believes that there will be a shift to the more sensitive methods as water systems realize that the analytical capabilities are available for a slighly increased analytical cost. (The ability to determine bromate concentrations as low as 1 Fg/L will provide water systems more information concerning the

optimization of ozone application to control for bromate formation.) EPA solicits comments as to whether laboratories should be required to switch to one of the more sensitive bromate methods for compliance monitoring sample analyses.

The final method that EPA is proposing to add today for DBPs is EPA Method 524.3 which is a purge and trap, gas chromatography, mass spectrometric method for TTHM and volatile organic compounds (VOCs). This method is a revision to EPA Method 524.2 that involves a change in the sample preservation technique. The currently approved method is used to analyze compliance monitoring samples for TTHM and VOCs. It requires samples to be dechlorinated using ascorbic acid and acidified with hydrochloric acid, in order to maintain sample integrity between collection and analysis. The acid must be added to the sample bottle after the sample is collected. Many samplers object to acidifying the samples when they are collected due to safety concerns over handling acid in the field. EPA Method 524.3 addresses this concern through the use of sodium bisulfate to adjust the sample pH to less than 2. The sodium bisulfate and ascorbic acid can both be added to the empty sample collection bottles in the laboratory, so they are present in the bottles when the sampler fills them. This eliminates the need for the sample collectors to carry and use acid in the field. EPA is proposing that EPA Method 524.3 be approved for use for both TTHM and VOC compliance monitoring. {A final determination on whether to propose this method will be made AFTER the holding study data are reviewed. We have to be sure this new preservation procedure works before it is proposed. If the preservation data are convincing, then method performance data will need to be discussed here for both TTHM and VOCs.}

c. Other parameters

Today's rule proposes to update the version of *Standard Methods* cited for alkalinity, magnesium, pH, TOC and UV_{254} determinations, to clarify which magnesium methods are approved for determining compliance with alternative criteria for TOC removal for enhanced softening systems, to update the citation for EPA Method 300.1 for bromide analyses, to add three new methods for bromide, and to add a new method for total organic carbon (TOC) and specific ultraviolet absorbance (SUVA).

The Stage 1 DBPR approved three TOC methods from the *Supplement* to the 19th edition of *Standard Methods* and one UV_{254} method from the 19th edition of *Standard Methods*. These methods are unchanged in the 20th edition, so EPA proposes to cite the 20th edition for these analyses in addition to the 19th edition. EPA also proposes that the 21st edition be cited in the final rule, if there are no substantive changes between the 20th and 21st editions for Standard Methods 5310 B, 5310 C, 5310 D, or 5910 B.

EPA Method 300.1 for bromide analyses is now included in an EPA methods manual that was published August 2000. The manual titled "Methods for the Determination of Organic and Inorganic Compounds in Drinking Water" is a compilation of methods developed by EPA for drinking water analyses. EPA Method 300.1 was previously only available as an individual method. EPA proposes to update the bromide method citation to the August 2000 methods manual so that the users are directed to the correct source of the method.

EPA Method 317.1, EPA Method 325.0, and ASTM Method D 6581-00 can be used to determine bromide in addition to chlorite and bromate. Since the methods are equivalent to EPA

Method 300.1 which was approved under the Stage 1 DBPR, EPA is proposing to add them as approved methods for bromide under today's rule.

Today's rule proposes to change the monitoring requirements for demonstrating eligibility to reduce bromate monitoring from monthly to quarterly. The Stage 1 DBPR allows the monitoring to be reduced if the system demonstrates that the average source water bromide concentration is less than 0.05 mg/L based upon monthly bromide measurements for one year. This rule proposes to change that requirement to a demonstration that the finished water bromate concentration is <0.005 mg/L as a running annual average. If this change is implemented, there will no longer be a need for bromide compliance monitoring methods. EPA is proposing additional bromide methods today in order to provide flexibility to the laboratories and water systems in the interim period before the Stage 2 DBPR compliance monitoring requirements becomes effective.

The Stage 1 DBPR allows systems practicing enhanced softening that cannot achieve the specified level of TOC removal, to meet instead one of several alternative performance criteria, including the removal of 10 mg/L magnesium hardness (as $CaCO_3$) from the source water. Analytical methods for measuring magnesium hardness were not included in the rule, but they were later promulgated in a Methods Update Rule (Federal Register, Vol 64, No 230, December 1, 1999, pages 67449-67467 (USEPA 1999b)). The December 1999 Methods Rule cited the magnesium methods at §141.23(k)(1), but it did not identify that these methods were to be used to demonstrate compliance with the alternative performance criteria specified in 141.135(a)(3)(ii). EPA is proposing to clarify this today by referencing the approved magnesium methods at §141.131(d)(6) and §141.135(a)(3)(ii).

Today's rule proposes to add EPA Method 415.3 as an approved method for total organic carbon (TOC) and specific ultraviolet absorbance (SUVA). The Stage 1 DBPR included three Standard Methods for TOC and one method for ultraviolet absorbance (UV_{254}). Additional quality control (QC) requirements were included for these measurements, because the methods did not contain the necessary criteria. The rule included instructions for calculating SUVA based on UV_{254} and dissolved organic carbon (DOC) analyses. The new EPA Method 415.3 includes the additional QC necessary to achieve reliable determinations for TOC, DOC, and UV_{254}. It clarifies how to handle samples which contain particulates and it describes a procedure for removing inorganic carbon from the sample prior to the organic carbon analysis. The method uses the same technologies as already approved. The advantage of this new method is that it documents the precision and accuracy that can be expected when proper QC procedures are implemented and it places all the necessary information for SUVA in one place.

EPA Method 415.3 provides sensitivity, precision and accuracy data for TOC and DOC measured using five different technologies:

(1) Catalyzed 680ºC combustion oxidation of organic carbon to carbon dioxide (CO_2) followed by nondispersive infrared detection (NDIR).

(2) High temperature (700 to 1100ºC) combustion oxidation followed by NDIR.

(3) Elevated temperature (95-100ºC) catalyzed persulfate digestion of organic carbon to CO_2 followed by NDIR

(4) UV catalyzed persulfate digestion followed by NDIR.

(5) UV catalyzed persulfate digestion followed by membrane permeation into a conductivity detector.

These technologies are included in the currently approved Standard Methods 5310 B and 5310 C. The new method indicates these technologies can provide detection limits between 0.02 mg/L and 0.25 mg/L. {The precision and accuracy data for TOC/DOC will be presented after additional experiments are completed. A discussion of UV & SUVA will also be added at that time.}

M. Laboratory certification and approval

EPA recognizes that the effectiveness of today's proposed regulation depends on the ability of laboratories to reliably analyze the regulated disinfection byproducts at the proposed MCLs. EPA has established a drinking water laboratory certification program that States must adopt as part of primacy. Laboratories must be certified in order to analyze samples for compliance with the MCLs. EPA has also specified laboratory requirements for analyses, such as alkalinity, bromide, disinfectant residuals, magnesium, TOC, and SUVA, that must be conducted by parties approved by EPA or the State. EPA's "Manual for the Certification of Laboratories Analyzing Drinking Water," EPA 815-B-97-001, March 1997, specifies the criteria which EPA uses to implement the drinking water laboratory certification program. Today's proposed rule maintains the requirements concerning laboratory certification for compliance with MCLs and all other analyses to be conducted by approved parties. Today's rule also proposes that TTHM and HAA5 analyses that are performed for the Initial Distribution System Evaluation (IDSE) be conducted by laboratories certified for those analyses.

The Stage 1 DBPR specified that in order to be certified the laboratory must pass an annual performance evaluation (PE) sample approved by EPA or the State using each method for which the laboratory wishes to maintain certification. The acceptance criteria for the DBP PE

samples were set as statistical limits based on the performance of the laboratories in each study. This was done because EPA did not have enough data to specify fixed acceptance limits.

Subsequent to the 1998 promulgation, EPA evaluated the results for the EPA Water Supply (WS) PE studies and the ICR PE studies to determine if fixed acceptance limits could now be applied. (Fixed limits were used during the ICR).

Four different fixed limits (±20%, ±30%, ±40%, and ±50% of the true value) were applied to each analyte in the WS PE study TTHM, HAA5, bromate, and chlorite samples. Successful analysis of the sample was defined as passing all four THMs in the TTHM PE sample; passing four of the five HAAs in the HAA5 PE sample; and passing bromate and chlorite individually. The number and percentage of laboratories that successfully passed each study sample were determined for the four fixed limits. These results were then evaluated to determine how narrow the criteria could be set in order to achieve accurate data and also provide enough certified laboratories to meet the capacity needs. Only the last six WS PE Studies administered by EPA (WS36 - WS41 conducted between 1996 - 1998) were used in the final recommendation, because they provided a better estimate of current laboratory capabilities. Table V.X summarizes the results of this WS PE Study evaluation.

The number of laboratories that analyzed WS TTHM PE samples was significantly larger than for the other DBPs, because a laboratory certification program for TTHM has been in effect since the promulgation of the THM rule in 1979. Most of the analytical methods for TTHM have been in use for many years, and the laboratories are experienced in their use. The Stage 1 DBPR established the first requirements to monitor for the other DBPs and certification isn't required until December 2001. Therefore, the WS PE results for HAA5, chlorite, and bromate

were from laboratories that were not part of a certification process and the laboratories were using methods that were relatively new. In addition, the method used for bromate during the WS studies was EPA Method 300.0 which is not as sensitive as EPA Method 300.1 which was promulgated with the Stage 1 Rule. Laboratories would be expected to have greater success in passing the bromate PE samples using Method 300.1 and the bromate methods that are being proposed in today's rule.

Table V.X. Fixed limit evaluation of WS PE studies 36 - 41 (average # and % of labs successfully completing studies).

DBP Sample	±20% of TV		±30% of TV		±40% of TV		±50% of TV	
	#Labs	%Labs	#Labs	%Labs	# Labs	%Labs	#Labs	%Labs
TTHM	609	73%	731	88%	773	93%	788	94%
HAA5[1]	50	37%	83	61%	103	75%	115	84%
chlorite	55	63%	68	78%	72	82%	74	85%
bromate	45	50%	52	57%	57	64%	60	68%

[1]Study 38 was excluded from this analysis, because a valid DCAA true value was not available for the HAA sample.

Based on the results from the above analyses, EPA believes it is reasonable to set the TTHM acceptance criteria at ±20% around the study true values. The number of laboratories capable of performing TTHM analyses is large and the above results show that in the time frame of 1996-1998, over 70% of the laboratories could successfully meet the ±20% criteria.

The data indicate that ±40% is probably the tightest criteria that could be used to evaluate HAA5 PE samples. Setting this criteria balances the need for approval of enough labs to meet monitoring capacity and the need to provide data of acceptable accuracy.

EPA believes chlorite PE samples should be evaluated using a ±30% criteria. Over 70% of the laboratories could meet this requirement for chlorite in the WS studies.

The percentage of passing labs for bromate is almost 60% when a ±30% criteria is applied to the WS study data. Since the data do not accurately reflect the bromate methods that are now being used by laboratories, EPA believes a greater percentage of laboratories would pass the bromate PE study using today's technology. Unfortunately, EPA does not have the data to verify this assumption, because EPA no longer conducts PE studies. Even if the assumption is

flawed, a 57% acceptance rate would still provide enough certified laboratories to handle the number of bromate samples required for compliance monitoring under the Stage 1 DBPR.

The proposed acceptance criteria are listed in Table V-X.

Table V-X. Proposed performance evaluation (PE) acceptance criteria

DBP	Acceptance Limits (percent)	Comments
TTHM		Laboratory must meet all 4 individual THM acceptance limits in order to successfully pass a PE sample for THMs
Chloroform	±20	
Bromodichloromethane	±20	
Dibromochloromethane	±20	
Bromoform	±20	
HAA5		Laboratory must meet the acceptance limits for 4 out of 5 of the HAA5 compounds in order to successfully pass a PE sample for HAA5
Monochloroacetic Acid	±40	
Dichloroacetic Acid	±40	
Trichloroacetic Acid	±40	
Monobromoacetic Acid	±40	
Dibromoacetic Acid	±40	
Chlorite	±30	
Bromate	±30	

EPA requests comments concerning the appropriateness of the proposed PE acceptance criteria.

EPA is also proposing that the above PE acceptance limits become effective within 60 days of promulgation of the final rule. This will allow the laboratory certification program to implement the fixed limits as soon as possible. Laboratories that were certified under the Stage 1 PE acceptance criteria would be subject to the new criteria when it is time for them to analyze their annual DBP PE samples(s).

Laboratories must also be able to measure the individual TTHM and HAA5 compounds at a level that is much lower than the MCL for these compound classes, since the MCL is based on a sum of the individual compound concentrations. The Stage 1 DBPR did not address the issue of detection, but the ICR did place minimum reporting level (MRL) requirements on laboratories. During the ICR, laboratories were required to report concentrations down to the MRL and meet specific accuracy and precision requirements at the MRL concentration. The ICR MRL concentrations were established based on two factors:

(1) Most of the samples were expected to contain concentrations greater than the respective MRLs or concentrations less than the MRL were not expected to be of health significance.

(2) Most laboratories were expected to be able to achieve the ICR precision and accuracy criteria at the MRL concentrations under normal operating conditions.

EPA evaluated the data from the ICR to determine if the laboratories were able to reliably measure down to the MRL concentrations. Precision and accuracy data from the calibration check standards prepared at the MRL concentrations (listed in Table V-X) were examined. The data indicated most laboratories were able to provide quantitative data for samples with these concentrations.

Table V-X. Proposed minimum reporting level (MRL) requirements

DBP	MRL (Fg/L)*	Comments
TTHM		
Chloroform	1	
Bromodichloromethane	1	
Dibromochloromethane	1	
Bromoform	1	
HAA5		
Monochloroacetic Acid	2	
Dichloroacetic Acid	1	
Trichloroacetic Acid	1	
Monobromoacetic Acid	1	
Dibromoacetic Acid	1	
Chlorite	200	
Bromate	5	Laboratories that use EPA Methods 317.1, 325.0, or 321.8 must meet a 1Fg/L MRL for bromate.

* The proposed MRL concentrations are the same as those used during the ICR with the exception of the proposed MRL for chlorite using any of the approved methods and for bromate using EPA Methods 317.1, 325.0, and 321.8.

As part of the request for certification, EPA is proposing to require laboratories to demonstrate they can reliably measure concentrations at least as low as the ones listed above in order to be certified for those parameters. This would mean the calibration curve must encompass the MRL concentration and the laboratory must verify the accuracy of the calibration curve at the lowest concentration for which quantitative data are reported by analyzing a calibration check standard at that concentration with each batch of samples. The measured concentration for this check standard should be within ±50% of the expected value. Laboratories may choose to report quantitative data at concentrations lower than the proposed MRLs as long as the precision and accuracy criteria are met by analyzing standards at the lowest reporting limit chosen by the laboratory.

Laboratories were not given the opportunity to report concentrations lower than the MRLs during the ICR. Several laboratories indicated they could have met the precision and accuracy criteria at lower concentrations, so EPA believes that each laboratory should set its own MRLs as long as the laboratory MRLs are not higher than the ones proposed in this rule.

The proposed MRL for MCAA is 2 Fg/L based on the ICR performance data. Most of the occurrence data from the ICR indicates that MCAA is generally not present at concentrations higher than this. Some laboratories reported that they could provide quantitative data for MCAA down to concentrations as low as 1 Fg/L. EPA solicits comments as to whether an MRL lower than 2 Fg/L is feasible for this compound and if so, what should that MRL concentration be?

EPA is proposing an MRL for chlorite which is much higher than can easily be achieved using the approved or proposed methods. The MRL specified during the ICR was 20 Fg/L and laboratories were able to successfully obtain quantitative data at that level. However, in the

context of this rule, EPA believes that requiring laboratories to verify their calibration curves down to 20 Fg/L each time samples are analyzed is unnecessary and burdensome. This is because chlorite analyses are only performed on samples from water plants that use chlorine dioxide. Most of the applied chlorine dioxide is converted to chlorite, so the concentrations that are expected in most compliance monitoring samples will be much higher than 20 Fg/L. (The ICR data showed a median chlorite concentration of 380 Fg/L in the finished water and 290 Fg/L as the distribution system average in systems using chlorine dioxide.) EPA is proposing an MRL of 200 Fg/L for chlorite, because most of the samples are expected to contain concentrations higher than 200 Fg/L. If a laboratory determines that the samples it is analyzing consistently contain chlorite concentrations that are <200 Fg/L, then EPA encourages it to set a lower MRL for its operations and provide quantitative data for lower concentrations. However, EPA believes this will not be necessary for most laboratories performing this analysis. EPA requests comments concerning whether an MRL for chlorite of 200 Fg/L is appropriate.

EPA is proposing two MRLs for bromate analyses in today's rule. This is because the traditional ion chromatographic (IC) methods using conductivity detection (USEPA Method 300.1 and ASTM Method 6581-00) are only capable of quantitating down to 5 Fg/L while the new IC methods using either post column reactions with UV/VIS detection (USEPA Methods 317.1 and 325.0) or IC followed by ICP-MS detection (USEPA Method 321.8) can reliably quantitate bromate concentrations as low as 1 Fg/L. EPA believes it is appropriate to set the MRL based on the capability of the method. If the MRL is based on the most sensitive method, then the routine IC methods could no longer be used even though they are adequate for demonstrating compliance with the bromate MCL. If the MRL is set using the least sensitive

method, then the option for reduced bromate monitoring based on a running annual average of <5 Fg/L would not be adequately demonstrated based on data reported with an MRL of 5 Fg/L. EPA solicits comments as to which of the above three MRL approaches should be considered for bromate.

EPA is proposing MRLs as part of the certification process in order to ensure that laboratories can reliably analyze samples that contain low concentrations of DBPs. Laboratories would be required to demonstrate these new MRL criteria when their current DBP certification is subject to renewal or if they are applying for certification for DBP methods for the first time. EPA is also proposing to require the MRLs be used for compliance reporting by the Public Water Systems when the data are used to support reduced monitoring requirements.

EPA requests comments concerning the appropriateness of the MRL certification requirements and whether additional requirements should be considered.

N. Consecutive system issues

The Stage 2 M-DBP Advisory Committee recognized that the structure of the Stage 1 DBPR allowed systems to be in compliance with the TTHM and HAA5 MCLs but still deliver water that exceeded the MCL on an annual average basis to certain parts of the distribution system because of the ability to average results across both time and locations. To address this, the Committee recommended that each monitoring location be required to meet the MCL (a locational running annual average), rather than allowing averaging over multiple locations.

The Committee also recognized that consecutive systems were an issue, since their status under the Stage 1 DBPR was interpreted differently by different States. Because this issue was addressed late in the negotiations and was complicated, the Committee made several general

recommendations, but left development of details to EPA as part of the rule proposal process. Specific language from the Advisory Committee is included in the following box.

3.1.c. Wholesale and Consecutive Systems

The FACA has considered the issues of consecutive systems and recommends that EPA propose that all wholesale and consecutive systems must comply with provisions of the Stage 2 DBPR on the same schedule required of the wholesale or consecutive system serving the largest population in the combined distribution system.

Principles:

- Consumers in consecutive systems should be just as well protected as customers of all systems, and
- Monitoring provisions should be tailored to meet the first principle.

The FACA recognizes that there may be issues that have not been fully explored or completely analyzed and therefore recommends that EPA solicit comments.

There is currently no formal definition of a consecutive system. EPA has used the term in its drinking water regulations infrequently - in 1975 in the initial Interim Primary Drinking Water Regulations (40 FR 59570, December 24, 1975); in 1998 in the Stage 1 Disinfectants and Disinfection Byproducts Rule (63 FR 69466, December 16, 1998); and in the 1998 Consumer Confidence Rule (63 FR 44526, August 19, 1998) and the 2000 Public Notification Rule (65 FR 26035, May 4, 2000)(both specified that sellers were to provide certain information to consecutive systems). EPA did not propose or promulgate a definition of "consecutive system" in any of these rulemakings.

Therefore, today EPA is proposing definitions for "consecutive system" and several other terms necessary to clarify the requirements in the proposed rule. These terms are defined in the following box.

Consecutive system is a public water system that buys or otherwise receives some or all of its finished water from another public water system on a regular basis (at least 60 days per year and not on an emergency basis).

Consecutive system entry point is a location where a consecutive system buys or otherwise receives some or all of its finished water from a wholesale system.

Combined distribution system is the totality of the distribution systems of all interconnected wholesale systems and consecutive systems.

Wholesale system is a public water system that sells or otherwise delivers finished water to another public water system on a regular basis (at least 60 days per year and not on an emergency basis).

1. Background

a. Why are there consecutive systems?

For many years, PWSs have bought and sold water to each other. Reasons include:

- saving money on pumping, treatment, equipment, and personnel;

- assuring an adequate supply during peak periods;

- acquiring emergency supplies;

- selling surplus supplies;

- delivering a better product to consumers;

- meeting federal and State standards; and

- forecasting budgets.

The consecutive system (the buyer) can maintain some degree of local control and revenue generation, address quality and quantity requirements, and control costs, while the seller gains a larger customer base and can use economies of scale by spreading costs over that base.

Also, EPA has encouraged States to promote system consolidation, with many small systems abandoning older treatment plants or poorer quality source waters and hooking up to a

system with more/better water, a larger base to spread treatment and compliance costs over, and better qualified operators.

b. 40 CFR 141.29

The first use of the term "consecutive system" was in the initial Interim Primary Drinking Water Regulations published on December 24, 1975 (40 FR 59570). The term was used in the title to §141.29, "Monitoring of consecutive public water systems", but was not used in the body of the section, which reads as follows:

> When a public water system supplies water to one or more public water systems, the State may modify the monitoring requirements imposed by this part to the extent that the interconnection of the systems justifies treating them as a single system for monitoring purposes. Any modified monitoring shall be conducted pursuant to a schedule specified by the State and concurred in by the Administrator of the U.S. Environmental Protection Agency.

2. Today's proposal

In addition to proposing several definitions, EPA is today proposing and requesting comments on requirements that consecutive systems must meet to comply with the Stage 2 DBPR. EPA is also proposing to allow (but not require) States to develop and implement a plan to modify monitoring requirements for consecutive systems to better target risks. The proposed requirements for consecutive systems are discussed in greater detail below.

a. Definitions

EPA is proposing to define a **consecutive system** as a public water system that buys or otherwise receives some or all of its finished water from another public water system on a regular basis (at least 60 days per year and not on an emergency basis). This definition will ensure that systems will be required to sample each source of water for TTHM and HAA5,

including those that are already treated. However, it would not require systems that receive water from a wholesale system for short periods of time to conduct monitoring for those sources.

EPA is proposing to define a **consecutive system entry point** as a location where a consecutive system buys or otherwise receives some or all of its finished water from a wholesale system. Since the proposed monitoring requirements are based on the number of plants that a system gets water from, today's proposal defines each consecutive system entry point as a treatment plant for the purpose of defining monitoring requirements. The State, either as part of the special primacy condition discussed later in the section, or after evaluating system-specific factors, may allow multiple entry points from a wholesale system to a consecutive system to be considered as a single treatment plant.

EPA is proposing to define a **combined distribution system** as the totality of the distribution systems of all interconnected wholesale systems and consecutive systems. EPA believes that this will allow for better decisionmaking by both systems and the State in developing monitoring and treatment requirements.

EPA is proposing to define a **wholesale system** as a public water system that sells or otherwise delivers finished water to another public water system on a regular basis (at least 60 days per year and not on an emergency basis). A system that both buys and sells finished water would be both a wholesale system and a consecutive system.

b. Responsibilities among parties

It is the responsibility of each system to comply with applicable drinking water regulations. As noted earlier, however, many consecutive systems abandoned their treatment plants because they wanted someone else to provide water that met standards, but did not want to give up the revenue stream or autonomy that having a billing system provided. Source water treatment by the wholesaler enabled many consecutive systems to meet these goals, since most contaminants do not increase in the distribution system. However, certain regulated contaminants do regularly increase in the distribution system and can be found at higher levels than those in the water entering the distribution system. These include lead and copper (usually through leaching from pipes), coliforms (regrowth in the system if favorable conditions exist), and some disinfection byproducts (when a disinfectant and DBP precursors continue to react in the distribution system).

Each affected system (including consecutive systems) must comply with the Stage 2 DBPR requirements, but EPA is proposing to leave the mechanism (e.g., contracts, State mediation, operating permits) to be determined on a case-by-case basis.

i. Initial distribution system evaluation

As explained in section V.G., consecutive systems of any size will be required to comply with the IDSE and Stage 2B requirements on the same schedule as the largest system in the combined distribution system. The Advisory recommended this provision because the most cost-effective way to achieve compliance with TTHM and HAA5 LRAAs is generally to treat at the source through some combination of precursor removal and alternative disinfectants. In order to make the best decisions concerning the treatment wholesale systems needed in order to

comply with LRAAs in both their own distribution systems and in consecutive systems, the wholesale system should know the TTHM and HAA5 levels throughout the combined distribution system served by the wholesale system. Without such DBP information, the wholesaler may design treatment changes that allow the wholesaler to achieve compliance, but leave the consecutive system no lower-cost compliance alternative. While this is possible even with the consecutive system DBP occurrence data, the Advisory Committee believed that the combinaton of data and State oversight would allow for the most cost-effective compliance strategies.

ii. Treatment and cost

There are techniques and procedures to minimize the formation and control the increase of TTHM and HAA5 in the distribution system. However, their application is complicated by the wholesale system - consecutive system relationship, especially when the wholesaler delivers water that meets standards to the consecutive system. The wholesale system has delivered water that complied with EPA standards when delivered and may not want to treat water beyond current standards (or absorb the costs associated with that treatment). EPA does not believe that most consecutive systems will want to replace the meter from the wholesaler with a treatment plant to address the particular contaminant. However, many States believe that these smaller systems would abandon the wholesaler and find their own source water to treat. Some States also believe that the wholesaler should be responsible for treatment upgrades to meet new drinking water standards.

However, the consecutive system also has responsibilities for ensuring compliance. The wholesaler generally has no control over the operation, maintenance, or detention time in the

distribution system of a consecutive system. These three factors greatly affect DBP formation and compliance.

Consecutive system compliance may require contracts to be renegotiated to account for the additional costs incurred by the wholesale system in treating the water to achieve compliance. Additional costs may be relatively low (in the case of a wholesale system required to make treatment changes to achieve compliance in both its own distribution system and that of the consecutive system) or high (in the case of a wholesale system that complies with Stage 2B in its own distribution system without any treatment changes, but must make changes for the consecutive system to comply). In the latter case, the consecutive system should evaluate alternatives to additional wholesale system treatment, such as line flushing and storage tank management to reduce distribution system residence time, alternative wholesale system sources, alternative water sources to use as a primary source, and use of chloramines as a residual disinfectant. Even if line flushing and storage tank management are not enough to achieve full compliance, these measures may lower DBP levels enough to allow for the wholesale system to select a less-expensive option to achieve compliance. When evaluating whether to develop an alternative primary water source (assuming one is available) instead of paying for additional treatment by the wholesale system, the consecutive system should review all costs associated with meeting all federal and State requirements, including capital, operations and maintenance, monitoring, staffing, and adequacy of quantity and quality to meet both current and future needs.

iii. Monitoring

The wholesale system often has the staff and training to conduct monitoring (both sampling and analysis). Although the wholesale system may monitor for a consecutive system,

the consecutive system is still responsible for ensuring that required monitoring is completed. This division of responsibilities may be addressed in both the contract between the wholesaler and consecutive system and in the DBP monitoring plans required of all systems.

iv. Violations

Under this proposal, monitoring and MCL violations are assigned to the PWS where the violation occurred. Several examples are included below:

- If a consecutive system has a contract with its wholesale system to monitor in the consecutive system, the consecutive system can sue the wholesale system for failure to conduct monitoring in violation of the contract. However, the consecutive system is still in violation because it had the legal responsibility for monitoring under State/EPA regulations.
- If a consecutive system's monitoring results indicate an MCL violation, the consecutive system is in violation because it had the legal responsibility for complying with the MCL under State/EPA regulations. If the contract with its wholesale system specifies that the delivered water has to meet certain quality specifications and it does not meet those specifications, the consecutive system can sue the wholesale system for failure to deliver water as specified in the contract.
- If a wholesale system has a violation, and provides that water to a consecutive system, the wholesale system is in violation. Whether the consecutive system is in violation may depend on the situation. Generally, the consecutive system will be in violation unless it conducted monitoring that showed that the violation was not present in the consecutive system.

v. Public notice and consumer confidence reports

The responsibilities for public notification and consumer confidence reports rest with each system. Under the Public Notice Rule and Consumer Confidence Report Rule, the wholesaler is responsible for notifying the consecutive system of violations and analytical results. Consecutive systems are required to conduct appropriate public notification after a violation and include results of the testing conducted by the wholesale system (unless the consecutive system had conducted equivalent testing) in its consumer confidence report.

c. Best available technology

EPA is proposing a BAT for consecutive systems that recognizes that treatment to remove already-formed DBPs is different than treatment to prevent or reduce their formation. See the BAT discussion in section V.C. for details.

d. State requirements.

i. Recordkeeping and reporting.

Consecutive systems are required to keep all records required of any other PWS regulated under this rule. They are also required to report to the State monitoring results, violations, and other actions, and are required to consult with the State after a peak excursion.

ii. Special primacy conditions

EPA is aware of the sometimes complicated wholesale system-consecutive system relationships that exist nationally and that there will be cases where the standard monitoring framework proposed today will not work well. Therefore, EPA is proposing to allow States to develop, as a special primacy condition, a program that would allow the State to modify monitoring requirements for consecutive systems in such a manner that would not undermine

public health protection and is consistent with the Advisory Committee recommendations. While this still require all systems (including consecutive systems) to comply with the TTHM and HAA5 LRAAs, it would allow the State to take into account complicated distribution systems where neighboring systems buy and sell from each other regularly throughout the year, water passes through multiple consecutive systems before it reaches a user, or a large group of interconnected systems have a complicated combined distribution system. EPA intends to develop a guidance manual to address development of a State program and other consecutive system issues.

e. Request for comments

EPA requests comment on all consecutive system issues related to this rule. Specifically, EPA requests comment on the following:

- Whether the proposed definitions adequately address various wholesale system - consecutive system relationships.

- Whether any additional terms need to be defined and, if so, what the definition should be.

- Whether the division of responsibilities is appropriate and conforms to any existing State practices.

- Whether the criteria for States' use of the special primacy criteria and other State responsibilities are appropriate.

O. Additional issues

In today's proposal, EPA is announcing its intention to modify the condition for a system that uses ozone (and therefore must monitor for bromate) to qualify for reduced bromate

monitoring from one sample per ozone plant per month to one sample per plant per quarter. In the Stage 1 DBPR, EPA required systems to demonstrate that source water bromide levels, as a running annual average, did not exceed 0.05 mg/L. EPA elected to use bromide as a surrogate for bromate in determining eligibility for reduced monitoring because the analytical method for bromate was not sensitive enough to quantify levels well below the bromate MCL of 0.010 mg/L.

In Section V.M., EPA proposed several new analytical methods for bromate that are far more sensitive than the existing method. Since these methods can measure bromate to levels of 0.001 mg/L or lower, EPA is proposing to replace the criterion for reduced bromate monitoring (source water bromide running annual average not to exceed 0.05 mg/L) with a bromate running annual average not to exceed either 0.005 mg/L or 0.0025 mg/L.

In the past, EPA has often set the criterion for reduced monitoring eligibility at 50% of the MCL, which would be 0.005 mg/L. However, as explained elsewhere in today's notice, the MCL for bromate is proposed to remain at 0.010 mg/L, a level that is higher than EPA's usual excess cancer risk range of 10(-4) to 10(-6) at 2x10(-4). EPA is considering both 0.005 mg/L and 0.0025 mg/L for the reduced monitoring criterion; the latter would allow greater confidence that the system has low levels of bromate.

Also, as discussed earlier, sodium hypochlorite solutions may contain significant levels of bromate. While EPA has no data to indicate that the use of sodium hypochlorite by itself would introduce bromate at levels near the bromate MCL, it is possible for the additional bromate from its use to affect either a system's compliance with the bromate MCL or its eligibility for reduced monitoring.

Request for comment

EPA requests comment on the issues discussed in this section. Specifically:

- What level should the criterion for reduced bromate monitoring be set at - 0.005 mg/L or 0.0025 mg/L? Why?

- Should EPA specify that systems that use both ozone and sodium hypochlorite monitor for bromate downstream of the addition of both?

VI. State Implementation

This section describes the regulations and other procedures and policies States would have to adopt to implement a Stage 2 DBPR, if finalized as proposed today. States must continue to meet all other conditions of primacy in 40 CFR Part 142.

The SDWA establishes requirements that a State or eligible Indian Tribe must meet to assume and maintain primary enforcement responsibility (primacy) for its public water systems. These SDWA requirements include: (1) adopting drinking water regulations that are no less stringent than federal drinking water regulations, (2) adopting and implementing adequate procedures for enforcement, (3) keeping records and making reports available on activities that EPA requires by regulation, (4) issuing variances and exemptions (if allowed by the State), under conditions no less stringent than allowed under the SDWA, and (5) adopting and being capable of implementing an adequate plan for the provisions of safe drinking water under emergency situations.

To implement the proposed Stage 2 DBPR, States are required to adopt the following proposed requirements under their own regulations:

– Section 141.201-209, Public Notification

– Section 141.64, MCLs for Disinfection Byproducts

– Subpart XXX, Disinfectant Residuals, Disinfection Byproducts, and Disinfection Byproduct Precursors.

In addition to adopting basic primacy requirements specified in 40 CFR Part 142, States may be required to adopt primacy provisions pertaining to specific regulations where implementation of the rule involves activities beyond general primacy provisions. The purpose of these provisions is to ensure state flexibility in implementing a regulation that (1) applies to specific system configurations within the particular state and (2) can be integrated with a State's existing Public Water Supply Supervision Program. States must include these rule distinct provisions in an application for approval or revision of their program. These primacy requirements for implementation flexibility are discussed in the following section.

A. State primacy requirements for implementation flexibility

To ensure that a State program includes all the elements necessary for an effective and enforceable program within that State under today's rule, a State primacy application must include a description of how the State will review IDSE reports and approve new or revised monitoring sites for long-term DBP compliance monitoring.

B. State recordkeeping requirements

The current regulations in §142.14 require States with primacy to keep various records, including analytical results to determine compliance with MCLs, MRDLs, and treatment technique requirements; system inventories; State approvals; enforcement actions; and the issuance of variances and exemptions. The proposed Stage 2 DBPR does not include any additional State recordkeeping requirements. However, today's proposal includes a revision to

the State recordkeeping requirements in §142.33 that clarifies the requirement that States must maintain records of monitoring plans submitted by public water systems.

C. State reporting requirements

EPA currently requires in § 142.15 that States report to EPA information such as violations, variance and exemption status, and enforcement actions. The proposed Stage 2 DBPR will not add any additional reporting requirements.

D. Interim primacy

On April 28, 1998, EPA amended its State primacy regulations at 40 CFR 142.12 to incorporate the new process identified in the 1996 SDWA Amendments for granting primary enforcement authority to States while their applications to modify their primacy programs are under review (63 FR 23362). The new process grants interim primary enforcement authority for a new or revised regulation during the period in which USEPA is making a determination with regard to primacy for that new or revised regulation. This interim enforcement authority begins on the date of the primacy application submission or the effective date of the new or revised State regulation, whichever is later, and ends when USEPA makes a final determination. However, this interim primacy authority is only available to a State that has primacy for every existing NPDWR in effect when the new regulation is promulgated.

As a result, States that have primacy for every existing NPDWR already in effect may obtain interim primacy for this rule, beginning on the date that the State submits the application for this rule to USEPA, or the effective date of its revised regulations, whichever is later. In addition, a State which wishes to obtain interim primacy for future NPDWRs must obtain primacy for this rule.

VII. Economic Analysis [Under Development]

VIII. Other Requirements

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

- Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, Tribal governments or communities;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof, or;
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of the Executive Order 12866, it has been determined that this rule is a “significant regulatory action” because it will have annual costs of more than $100 million. As such, this action was reviewed by OMB . Changes made in response to OMB suggestions or recommendations are documented in the public record. EPA prepared an Economic Analysis (EA) pursuant to Executive Order 12866 and a revised version of the EA is in the docket for this rule (USEPA , 2001d).

B. Regulatory flexibility analysis

1. Background

The Regulatory Flexibility Analysis (RFA), 5 U.S.C. 601 et seq., as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, generally requires an agency to prepare an Initial Regulatory Flexibility Analysis (IRFA) for a proposed rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. To determine whether to certify the Stage 2 DBPR or conduct an IRFA, EPA conducted a preliminary screening analysis (USEPA, 2001n). Under IRFA small entities include small businesses, small organizations, and small governmental jurisdictions.

2. Use of alternative definition

The RFA provides default definitions for each type of small entity. It also authorizes an agency to use alternative definitions for each category of small entity, "which are appropriate to the activities of the Agency after proposing the alternative definition(s) in the Federal Register and taking comment." 5 U.S.C. secs. 601(3) - (5). In addition, agencies must consult with SBA's Chief Council for Advocacy to establish an alternative small business definition.

EPA is proposing the Stage 2 DBPR, which contains provisions that also apply to small PWSs serving fewer than 10,000 persons. This is the cut off level specified by Congress in the 1996 Amendments to the Safe Drinking Water Act for small system flexibility provisions. Because this definition does not correspond to the definitions of small for small businesses, governments, and nonprofit organizations, EPA requested comment on an alternative definition

of a small entity in the preamble to the proposed Consumer Confidence Report (CCR) regulation (63 FR 7620, February 13, 1998). Comments showed that stakeholders support the proposed alternative definition. EPA also consulted with the SBA Office of Advocacy on the definition as it relates to small business analysis. In the preamble to the final CCR regulation (63 FR 4511, August 19, 1998), EPA stated its intent to establish this alternative definition for regulatory flexibility assessments under the RFA for all drinking water regulations and has thus used it in this proposed rulemaking.

3. Initial Regulatory Flexibility Analysis

As part of its screening analysis, EPA evaluated the potential economic impact of the rule on small entities by comparing compliance costs as a percentage of sales, revenues, and operating expenses for each small entity classification. In addition, EPA conducted a quantitative analysis of small systems impact as a result of the Stage 2 DBPR. Based on the information presented in Table VIII-1, EPA has determined that the Stage 2 DBPR will not lead to significant economic impacts (i.e., costs equal to or higher than 1 percent of revenues or expenditures) for a substantial number of small entities and, therefore, does not need to conduct an IRFA.

Table VIII.1. Annualized compliance cost as a percentage of revenues or expenditures for all small entities.

Entity	Number of Small Systems (A)	Average Annual Estimated Revenues or Expenditures per System ($)(B)	Average Annual Compliance Cost per System ($) (C)	Cost/ Revenue (C/B)
Small Governments	16,286	$2,333,119	$693	0.03%
Small Businesses	19,861	$2,314,190	$693	0.03%
Small Organizations	3,575	$4,301,574	$693	0.02%
All Small Entities (50% small business, 41% small government, 9% small organization)	39,721	$2,449,667	$693	0.03%

Despite EPA's certification that the Stage 2 DBPR will not lead to a significant economic impacts for a substantial of small entities, the Agency conducted extensive evaluations on how to minimize the impact of the rule on small entities. Although an IRFA was not required, EPA evaluated many criteria similar to those that would have been required for an IRFA.

a. Reasons the Agency is considering this action

There are over 48,000 public water systems in the United States that disinfect their water. Disinfectants are an essential element of drinking water treatment, however, they react with naturally-occurring materials in the water to form byproducts which may pose health risks. Both epidemiology and toxicology studies have found that DBPs are a potential health hazard. These studies have raised concern regarding potential cancer and reproductive and developmental risks

from exposure to DBPs and chlorinated drinking water. The M-DBP Advisory Committee, which was formed to advise EPA on the development of microbial and disinfection byproduct regulation agreed with the need for the Stage 2 DBPR to reduce potential risks, especially reproductive and developmental risks from DBPs. EPA is therefore proposing the Stage 2 DBPR and the LT2ESWTR to further mitigate the potential health hazards of DBPs and microbial contaminants, especially *Cryptosporidium*.

b. The objectives of, and the legal basis for, the proposed rule

As part of the 1996 amendments to the SDWA, Congress required the U.S. EPA to develop a Stage 2 DBPR under Section 1412(b)(2)(C) which focuses on public water systems disinfect their water. The 1996 amendments requires EPA to finalize a Stage 2 DBPR by May 2002. The goal of stage 2 DBPR is to prevent potential health effects from DBPs beyond that controlled for by the 1979 TTHM Rule and the Stage 1 DBPR.

c. Number and types of small entities to which the rule will apply

For purposes of assessing the impacts of today's rule on small entities, a small entity is defined by systems serving fewer than 10,000 people. The small entities directly regulated by this proposed rule are public water systems that treat their water with a chemical disinfectant for either primary or residual treatment or distribute water that has been treated. Under the proposed option, the Agency has determined that the final rule would result in approximately 1,603 small systems needing capital improvement, approximately 860 small systems would need to significantly change their disinfection practices, and approximately 37 small systems would need to make capital improvements to advanced. A discussion of the impacts on small entities is described in more detail in chapters six and eight of the Regulatory Impact Analysis of the Stage

2 DBP EA (USEPA, 2001d). A discussion of the impacts on small entities is described in more detail in chapters six and eight of the Economic Analysis of the Stage 2 DBP EA (USEPA, 2001d). Table VIII.2 shows the impacts of the Stage 2 DBPR on the small entities.

Table VIII.2. Annual compliance costs at 3 percent discount rate for the proposed Stage 2 DBPR by system size and type

System Type	Systems Size/Population Served				
	<100	101-500	500-1,000	1000-3,300	3,300-<10K
Publicly-Owned	$98,675	$880,656	$1,001,023	$3,937,435	$6,128,000
Privately-Owned	$558,668	$1,342,016	$440,065	$866,775	$733,169
All Systems	$657,344	$2,222,672	$1,441,088	$4,804,210	$6,861,169

d. Coordination with other federal rules

EPA issued a final Stage 1 DBPR in November 1998, a proposed LT1ESWTR in November 2000, a FBR in September 2000, and a proposed GWR in November 2000, as required by the Safe Drinking Water Act Amendments of 1996. The Stage 1 DBPR applies to community water systems and non-transient non-community water systems, including those that serve less than 10,000 people, that add a disinfectant to the drinking water during any part of the treatment process or deliver water containing a disinfectant. The proposed LT1ESWTR which applies to surface water serving less then 10,000 people improves control of microbial pathogens in drinking water systems including *Cryptosporidium*, and preventing increases in microbial risks while PWSs control for disinfection byproducts. The FBR will require certain PWSs to institute changes to the return of recycle flows within the treatment process to reduce the effects of recycle on compromising microbial control. Finally, the GWR requires a targeted risk-based regulatory strategy for all ground water systems. None of these regulations duplicate, overlap or conflict with this proposed rule.

e. Minimization of economic burden

As a result of the input received from stakeholders, the EPA workgroup, the M-DBP Advisory Committee, and other interested parties, EPA has developed a locational running annual average (LRAA) of 0.80 and 0.60 mg/L for TTHM and HAA5 respectively, and in combination with Initial Distribution Systems Evaluations (IDSE) as the preferred option. LRAAs are simply running annual averages calculated for each sample location in the distribution system. In addition to meeting the MCLs for TTHM and HAA5, systems will be required to conduct IDSEs. The purpose of the IDSE is to identify compliance monitoring sites

with the highest TTHM and HAA5 levels to be found in the distribution system. According to the Stage 2 DBPR EA (USEPA, 2001d), only 17% of small community water systems will conduct IDSE monitoring because small NTNCWSs are exempt from IDSE monitoring, systems serving fewer than 500 people may receive a waiver from their States/Primacy Agencies, and other systems will have the option to substitute existing systems data demonstrating that all samples have been below 40 and 30 ug/L for TTHM and HAA5 respectively in the last 2 years. This option is described in more detail in section V.C. of this preamble.

On an annual basis, the cost of the proposed alternative ranges from $88.4 million to $104.7 million using a three and seven percent discount rate, respectively. System costs make up 99 percent of the total rule costs with 32 percent of the cost attributable to small systems. The preferred Alternative was recommended by the M-DBP Advisory Committee because it addresses the objectives for reduced adverse reproductive and developmental health effects by controlling peak levels of TTHM and HAA5 concentrations throughout the distribution systems without compromising microbial protection and without requiring most systems to face the high cost of employing additional advanced technologies. The costs of such advanced technologies are most burdensome for small systems. The Preferred Alternative is the least costly alternative and, at the same time, should reduce peak DBP levels, which appear to pose the greatest adverse reproductive and developmental health risks, as well as average levels which pose cumulative risk from chronic exposure.

4. Small entity outreach and small business advocacy review panel

As required by section 609(b) of the RFA, as amended by SBREFA, EPA has conducted outreach to small entities and convened a Small Business Advocacy Review Panel to obtain

advice and recommendations from representatives of the small entities that potentially would be subject to this rule's requirements. The Small Business Advocacy Review (SBAR) Panel members for the Stage 2 DBPR were: the Small Business Advocacy Chair of the Environmental Protection Agency, the Chief of the Standards and Risk Reduction Branch of the Office of Ground Water and Drinking Water within EPA's Office of Water, the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Chief Counsel for Advocacy of the Small Business Administration. The Panel convened on April 25, 2000, and met 5 times before the end of 60-day Panel period on June 23, 2000. The SBAR Panel's report, "Final Report of the Small Business Advocacy Review Panel on Stage 2 Disinfectants and Disinfection Byproducts Rule (Stage 2 DBPR) and Long-term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR)", the Small entity representatives (SERs) comments on components of the Stage 2 MDBP Rules, and the background information provided to the SBAR Panel and the SERs are available for review in the Office of Water Docket.

Before convening the SBAR Panel, EPA consulted with a group of 24 SERs likely to be impacted by the Stage 2 M-DBP Rules. The SERs included small system operators, local government officials, and small nonprofit organizations. The SERs were provided with background information on the Safe Drinking Water Act, Stage 1 DBPR, IESWTR, Stage 2 options and unit cost analyses resulting from using different technologies to meet the required MCLs in preparation for the teleconferences on January 28, 2000, February 25, 2000, and April 7, 2000. This information package included data on options and preliminary unit costs for treatment enhancements under consideration. It is important to note that, since EPA did not initiate considering the IDSE requirements until after these consultations with SERs and the

SBAR panel, no comments were therefore received on the IDSE requirements from either SERs or the SBAR panel.

The information was discussed with SERs during these conference calls and EPA provided feedback and took notes of any initial SER comments. Following the calls, the SERs were asked to provide input on the potential impacts of the rule from their perspective. Seven SERs provided written comments on these materials. These comments were provided to the SBAR Panel when the Panel convened in April 25, 2000. After a teleconference between the SERs and the Panel on May 25, 2000, the SERs were invited to provide additional comments on the information provided. Seven SERs provided additional comments on the rule components after the teleconference.

In general, the SERs consulted on the Stage 2 M-DBP rules were concerned about the impact of these proposed rules on small water systems, small systems ability to acquire the technical and financial capability to implement requirements, maintaining flexibility to tailor requirements to their needs, and the limitations of small systems.

Consistent with the RFA/SBREFA requirements, the Panel evaluated the assembled materials and small-entity comments on issues related to the elements of the IRFA. The following is a summary of the Panel report. A copy of the Panel report is included in the Office of Water docket for this proposed rule.

a. Number of small entities to which the rule will apply

EPA has estimated that there are 39,722 small public water systems (4,673 surface water and 35,049 ground water systems) that disinfect their water and could be affected by the Stage 2 DBPR, serving a population of more than 36 million. The Panel did not make any

recommendation on the applicability of the Stage 2 DBPR. A more detailed discussion of the impact of the proposed rule on small entities can be found in Section VII of this preamble.

b. Recordkeeping and reporting and other compliance requirements

Today's proposal takes into consideration the recordkeeping and reporting concerns identified by the Panel and the SERs. The Panel recommended that EPA evaluate ways to minimize the recordkeeping and reporting burdens under the rule by ensuring that States have appropriate capacity for rule implementation and provide as much monitoring flexibility as possible to small systems. EPA believes that continuity with the Stage 1 DBPR was maintained to the extent possible to ease the transition to the Stage 2 DBPR, especially for small systems. EPA's decision to maintain the same MCLs for TTHM and HAA5 will also help to minimize the additional implementation burden. Generally, routine monitoring will be similar in frequency to monitoring for the Stage 1 DBPR, and systems with low DBP levels will still be eligible for reduced monitoring. Many systems will conduct the same amount of monitoring for the Stage 2 DBPR as for the Stage 1 DBPR. Surface and ground water community water systems (CWSs) serving 500 to 9,999 people and all ground water systems serving at least 10,000 people may be required to add one sampling site and take an additional quarterly TTHM/HAA5 sample at that site. Systems already exempt from any monitoring under the Stage 1 DBPR will have no additional monitoring under the Stage 2 DBPR. As noted before, some small systems will be effectively complying with such requirements under Stage 1 anyway, so making it the formal basis for compliance would not impose any additional burden on some small systems.

The Panel also noted the concern of several SERs that flexibility should be provided in the compliance schedule of the rule. SERs noted the technical and financial limitations that

some small systems will have to address, the significant learning curve for operators with limited experience, and the need to continue providing uninterrupted service as reasons why additional compliance time may be needed for small systems. The panel encouraged EPA to keep these limitations in mind in developing the proposed rule and provide as much compliance flexibility to small systems as is allowable under the SDWA. EPA believes that the proposed compliance schedules provides sufficient time for small systems to achieve compliance.

Under the proposed LT2ESWTR, certain subpart H systems with low levels of indicators, such as E. *coli,* will not have to monitor for *Cryptosporidium.* Thus, small systems E.*coli* monitoring cannot be initiated until large and medium system monitoring has been completed. The compliance time line for small systems thus lag 1.5 to 2.5 years behind the large and medium systems time line. In addition, if capital improvements are necessary for a particular PWS, the SDWA allows a State to allow the system up to an additional two years to comply with the regulation. The Agency is developing guidance manuals to assist small entities with their compliance efforts.

c. Interaction with other federal rules

The Panel is unaware of any Federal rules that would duplicate or overlap with the proposed rule. There are a number of existing rules that are closely associated with the rules under development. These include the THMR, SWTR, IESWTR, Stage 1 DBPR, LT1ESWTR, FBR, and GWR. The Panel is unaware of the potential conflict between rules regulating control of microbial contaminants and those regulating disinfection byproducts, as well as between those regulating DBPs and other treatment needs that may require preoxidation.

d. Regulatory alternatives

The Panel considered a wide range of options and regulatory alternatives for providing small businesses with flexibility in complying with the Stage 2 DBPR. The Panel considered a wide range of options and regulatory alternatives for providing small businesses with flexibility in complying with the Stage 2 DBPR. The Panel recognized the concern shared by most stakeholders regarding the needs to reduce DBP variability in the distribution system. This concern comes from recent studies which, while not conclusive, suggest that there may be adverse reproductive effects associated with relatively short-term exposure to DBPs. In general, this is less of a concern for small systems because even under Stage 1 DBPR, most will be monitoring at only a single point in the distribution system (which represents the point of maximum TTHM exposure), and many will be monitoring only once during the year, at a time which corresponds to the season with the highest potential occurrence. Thus, these systems are effectively complying with a single highest maximum. It is important to note that based on the IDSE results, some small systems will have a high TTHM site that is different from the HAA5 site. These systems need to monitor at 2 sites under the Stage 2 DBPR. EPA believes that, an approach based on compliance with an 80/60 LRAA appears to be an effective way of addressing concerns regarding locational variability.

Regarding seasonal variability, the Panel was concerned about a regulatory alternative requiring compliance with an 80/60 single highest (SH), because it would impose significant additional cost on some small systems. The Panel recommended that EPA instead explore an approach under which individual high values might trigger additional assessment and/or notification requirements, rather than a MCL violation.

EPA agrees with the panel recommendations on the occurrence of the peak values. Under today's proposal, public water systems are required to maintain a record of TTHM and HAA5 concentrations detected at each sample location. As part of the sanitary survey process, systems are required to consult with their State/primacy agency regarding peaks in TTHM and HAA5 occurrence that have occurred (a peak is defined as any sample level 25% over the MCL). EPA is developing guidance for public water systems and States on how to conduct peak excursion evaluations, and how to reduce peak excursions of DBP levels through actions such as distribution system operational changes (Section V.C.).

The Panel noted the strong concerns expressed by some SERs about the uncertainty in the current scientific evidence regarding health effects from exposure to DBPs, particularly regarding short term exposure. A Panel member recommended that, EPA give further serious consideration to making a determination that the currently available scientific evidence does not warrant imposing additional regulatory requirements, beyond Stage 1, at this time. This Panel member recommended that EPA instead continue to vigorously fund ongoing research into health effects, occurrence, and appropriate treatment techniques for DBPs, and reconsider whether additional requirements are appropriate during its next SDWA required six-year review of the standard. This panel member also recommended that EPA separately explore whether adequate data exist to warrant regulation of NTNCs at a national level at this time.

EPA has considered these recommendation and believes the Stage 2 DBPR is needed to protect public health. EPA's main mission is the protection of human health and the environment. When carrying out this mission, EPA must often make regulatory decisions with less than complete information and with uncertainties in the available information. EPA believes

it is appropriate and prudent to err on the side of public health protection when there are indications that exposure to a contaminant may present risks to public health, rather than take no action until risks are unequivocally proven. Therefore, while recognizing the uncertainties in the available information, EPA believes that the weight of evidence represented by the available epidemiology and toxicology studies on chlorinated water and DBPs supports a hazard concern and a protective public health approach to regulation.

C. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. An Information Collection Request (ICR) document has been prepared by EPA (ICR No.) and a copy may be obtained from Sandy Farmer by mail at Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW, Washington, DC 20460, by email at farmer.sandy@epamail.epa.gov, or by calling (202) 260-2740. A copy may also be downloaded off the Internet at http://www.epa.gov/icr.

The information collected as a result of this rule will allow the States and EPA to determine appropriate requirements for specific systems, and to evaluate compliance with the rule. For the first three years after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], the major information requirements pertain to preparation for monitoring activities, and for compliance tracking. The information collection requirements are mandatory (Part 141). The information collected is not confidential.

The preliminary estimate of aggregate annual average burden hours for Stage 2 DBPR for systems and States is 244,278 hours. Annual average aggregate cost estimate is $16.5 million

for operation and maintenance as a purchase of service for lab work. The burden hour per response is 2.51 hours. The frequency of response (average responses per respondent) is 6.5 annually. The estimated number of likely respondents is 15,006 (the product of burden hours per response, frequency, and respondents does not total the annual average burden hours due to rounding).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information; processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments on the ICR to the Director, Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., N.W., Washington, DC

20503, marked "Attention: Desk Officer for EPA." Include the ICR number in any correspondence. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after [Insert date of publication in the FEDERAL REGISTER], a comment to OMB is best assured of having its full effect if OMB receives it by [Insert date 30 days after publication in the FEDERAL REGISTER]. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

D. Unfunded Mandates Reform Act

1. Summary of UMRA requirements

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under UMRA section 202, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed, under section 203 of the UMRA, a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local and Tribal governments, in the aggregate, or the private sector in any one year. Thus today's proposed rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Today's rule applies to all systems regardless of size; therefore, it is not unique as it provides a comparable level of health protection to individuals served by either small or large sized systems. While there are small differences between the monitoring requirements for small and large sized systems, these differences reflect an effort to reduce burden for small systems while still maintaining a comparable level of health protection.. Thus, today's rule is not subject to the requirements of section 203 of UMRA.

Nevertheless, EPA has tried to ensure that State, local, and Tribal governments had opportunities to provide comment. EPA consulted with small governments to address impacts of regulatory requirements in the rule that might significantly or uniquely affect small governments. As discussed next, a variety of stakeholders, including small governments, were provided the opportunity for timely and meaningful participation in the regulatory development process. EPA

used these opportunities to notify potentially affected small governments of regulatory requirements being considered. Consistent with the intergovernmental consultation provisions of section 204 of UMRA, EPA held, prior to proposal , consultations with the governmental entities affected by this rule. EPA held three conference calls for stakeholders prior to proposal. The Agency convened a Small Business Advocacy Review (SBAR) Panel in accordance with the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) to address small entity concerns, including small local governments. EPA consulted with small entities representatives (SERs) prior or convening the Panel to get their input on the Stage 2 DBPR. Eight of the small entities represented small governments. A detailed description of the SBREFA process can be found in Section II C.2 and VIII of this preamble.

In addition, to inform and involve Tribal governments in the rulemaking process, EPA consulted with them ealry in the process as described in Section VIII.J.

In addition, EPA will educate, inform, and advise small systems, including those run by small governments, about the Stage 2 DBPR requirements. EPA has engaged in consultation with local governmental organizations as described in Section VIII I. The Agency is developing plain-English guidance that will explain what actions a small entity must take to comply with the rule. Also, the Agency has developed fact sheets that concisely describe various aspects and requirements of the proposed Stage 2 DBPR. These fact sheets are available by calling the Safe Drinking Water Hotline at 800-426-4791.

E. National technology transfer and advancement act

Under section 12(d) of the National Technology Transfer and Advancement Act (NTTAA), the Agency is required to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. Where available and potentially applicable voluntary consensus standards are not used by EPA, the Act requires the Agency to provide Congress, through OMB, an explanation of the reasons for not using such standards.

EPA's process for selecting the analytical test methods is consistent with section 12(d) of the NTTAA. In preparing today's proposed rule, EPA searched for consensus methods that would be acceptable for compliance determinations under the SDWA for the measurement of disinfectants, DBPs, and other parameters. As a result of that review, EPA is proposing one new method from ASTM. In the Stage 1 DBPR, EPA promulgated 14 methods from the Standard Methods Committee for measuring disinfectants, DBPs, and other parameters. Today's rule proposes to add the most recent versions of these 14 methods as approved methods.

F. Executive order 12898: Environmental justice

Executive Order 12898 establishes a Federal policy for incorporating environmental justice into Federal agency missions by directing agencies to identify and address disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority and low-income populations. The Agency has considered environmental justice related issues concerning the potential impacts of this action and consulted with minority and low-income stakeholders.

This preamble has discussed how the Stage 1 DBPR served as a template for the development of the Stage 2 DBPR. As such, the Agency also built on the efforts conducted during the Stage 1 DBPR development to comply with E.O. 12898. On March 12, 1998, the Agency held a stakeholder meeting to address various components of pending drinking water regulations and how they may impact sensitive sub-populations, minority populations, and low-income populations. Topics discussed included treatment techniques, costs and benefits, data quality, health effects, and the regulatory process. Participants included national, State, tribal, municipal, and individual stakeholders. EPA conducted the meetings by video conference call between eleven cities. This meeting was a continuation of stakeholder meetings that started in 1995 to obtain input on the Agency's Drinking Water Programs. The major objectives for the March 12, 1998 meeting were:

(1) Solicit ideas from stakeholders on known issues concerning current drinking water regulatory efforts;

(2) Identify key issues of concern to stakeholders, and;

(3) Receive suggestions from stakeholders concerning ways to increase representation of communities in OGWDW regulatory efforts.

In addition, EPA developed a plain-English guide specifically for this meeting to assist stakeholders in understanding the multiple and sometimes complex issues surrounding drinking water regulation.

The Stage 2 DBPR applies to community water systems and nontransient noncommunity water systems that apply a chemical disinfectant or deliver water that has been chemically

disinfected. Consequently, the health protection from DBP exposure that this rule provides is equal across all income and minority groups served by systems regulated by this rule.

G. Executive order 13045: Protection of children from environmental health risks and safety risks

Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks" (62 F.R. 19885, April 23, 1997) applies to any rule that: (1) is determined to be economically significant as defined under E.O. 12866, and; (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This proposed Stage 2 DBPR is not subject to E.O. 13045 because the Agency does not have reason to believe the environmental health risks or safety risks addressed by this action present a disproportionate risk to children. Nonetheless, we have evaluated the environmental health or safety effects of disinfection byproducts found in drinking water on children.

For each of the DBPs included in the proposed Stage 2 DBPR, EPA has compiled analyses of the available data used for deriving the MCLG to determine if these values are protective for fetuses and children.

The observed adverse effects in most of the available studies are at higher doses than the established MCLGs for these contaminants. We have analyzed the available toxicological and epidemiological data in the report entitled, *Disinfection Byproduct Technical Review Panel Report Health Risks to Fetuses, Infants and Children* (USEPA, 2001). In the report, we note that BDCM, bromoform, DCAA, and bromate are considered likely carcinogens for humans.

MCLGs of zero were selected after consideration of the potential carcinogenicity of these chemicals. These MCLGs are protective for both children and adults. The MCLGs for chloroform, DBCM, MCAA, and TCAA were based on systemic toxicity. The NOAEL/LOAELs used to derive thse numbers are lower than the NOAEL/LOAELs for developmental effects; and thus are protective of the unborn fetus, infants and children for developmental malformations for exposure to these DBPs. The data on MBAA and DBAA are insufficient for the derivation of an MCLG. Therefore, it can be concluded that the Agency does not have reason to believe that the environmental health risks or safety risks addressed by the action in this proposed rule present a disproportionate risk to children. Similarly, the MCLGs of all DBPs in the proposed Stage 2 DBPR are protective of fetuses, infants and children from potential adverse developmental/reproductive effects.

The public is invited to submit or identify peer-reviewed studies and data, of which EPA may not be aware, that assessed results of early life exposure to DBPs.

H. Consultation with the science advisory board, national drinking water advisory council, and the secretary of health and human services

EPA met with the Science Advisory Board (SAB) on June 13, 2001 and September 25-26, 2001 to discuss the proposal. In accordance with section 1412 (d) and (e) of the Act, the Agency has submitted the proposed Stage 2 DBPR to the Science Advisory Board, National Drinking Water Advisory Council (NDWAC), and the Secretary of Health and Human Services for their review. EPA will consider the comments received from these groups in developing the final Stage 2 DBP rule.

I. Executive order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Under section 6(b) of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. Under section 6(c) of Executive Order 13132, EPA may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

EPA has concluded that this proposed rule may have federalism implications. This proposed rule may have more than minimal adverse impacts on State and local governments in that their annual costs for implementation are expected to be over $104 million at a 7 percent discount rate (and over $88 at a 3 percent discount rate). However, it will not impose substantial direct compliance costs on State or local governments, nor will it preempt State law. Thus, the requirements of sections 6(b) and 6(c) of the Executive Order do not apply to this rule.

Consistent with EPA policy, EPA nonetheless consulted with State and local officials early in the process of developing the proposed regulation to permit them to have meaningful and timely input into its development. On February 20, 2001, EPA held a governmental dialogue with representatives of state and local organizations including those that represent elected officials. At the consultation meeting, questions ranged from a basic inquiry into how *Cryptosporidium* gets into water to more detailed queries about anticipated implementation guidance, procedures, and schedule. No concerns were expressed. Some of the state and local organizations, who attended the governmental dialogue on upcoming microbial and disinfection byproduct rulemakings were also participants in the Federal Advisory Committee meetings and signed the Agreement in Principle. In addition, EPA has consulted with a mayor in the SBREFA consultation which is described in section VIII A.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

J. Executive Order 13175: Consultation and coordination with Indian Tribal governments

(A different template may be chosen once the Executive Order 13175 guidance has been finalized.) Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 6, 2000), requires EPA to develop "an accountable process to ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes."

Under Executive Order 13175, EPA may not issue a regulation that has tribal implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by tribal governments, or EPA consults with tribal officials early in the process of developing the proposed regulation and develops a tribal summary impact statement.

EPA has concluded that this proposed rule may have tribal implications, because it may impose substantial direct compliance costs on tribal governments, and the Federal government will not provide the funds necessary to pay those costs. Accordingly, EPA provides the following tribal summary impact statement as required by section 5(b) of Executive Order 13175. EPA consulted with tribal officials early in the process of developing this regulation to permit them to have meaningful and timely input into its development. EPA

consulted with Tribes in a variety of ways. The most extensive participation of Tribes was on the M-DBP Advisory Committee through a representative of the All Indian Pueblo Council which is associated with about 20 Tribes. In February 1999, at the Las Vegas EPA/Inter-Tribal Council of Arizona, this Tribal Advisory Committee member was requested by a number of Tribal representatives to be the Advisory Committee representative for Federal Tribes, given his knowledge about drinking water systems. The All Indian Pueblo Council also presented the Agreement in Principle prior to signature in at least one political forum for various Tribes not affiliated with AIPC.

EPA presented the Stage 2 DBPR at three venues: the 16th Annual Consumer Conference of the National Indian Health Board, the annual conference of the National Tribal Environmental Council, and the EPA/Inter Tribal Council of Arizona, Inc. tribal consultation meeting. Over 900 attendees representing Tribes from across the country attended the National Indian Health Board's Consumer Conference and over 100 Tribes were represented at the annual conference of the National Tribal Environmental Council. At the first two conferences, an EPA representative conducted two workshops on EPA's drinking water program and upcoming regulations, including the Stage 2 DPBR.

At the EPA/Inter Tribal Council of Arizona meeting, representatives from 15 Tribes participated. The presentation materials and meeting summary were sent to over 500 Tribes and tribal organizations.

EPA also made a presentations at the National Tribal Environmental Council's Annual Conference on April 2000 about upcoming drinking water regulations including the Stage 2 DBP proposed rule. Fact sheets describing the requirements of the proposed rule and requesting

Tribal input were distributed in an Annual EPA Tribal meeting in San Francisco and at a Native American Water Association meeting in Scottsdale, Arizona, both in 2000. EPA also worked through its Regional Indian Coordinators and the National Tribal Operations Committee to raise awareness of the development of the proposed rule. In addition, in November 2000 EPA mailed to all Federal Tribes the fact sheets describing the upcoming proposed rulemaking.

A few Tribes responded by requesting more information and expressing concern about having to implement too many regulations. Members of the Tribal Caucus of the National Tribal Operations Committee provided comment. Those who provided comment noted that the rule would certaintly have a benefit. They also expressed a concern about infrastructure costs and that no funding was attached to the rule.

In response to tribal input, EPA did explain the health protection benefit expected to be gained by this proposed rule to one tribal representative who responded to the November 2000 mailout. EPA also directed those who asked for more information to the Agreement in Principle on the EPA website.

Section 1412 (b)(2)(C) of the Safe Drinking Water Act requires EPA to promulgate a Stage 2 Disinfectants/Disinfection Byproducts Rule by May 2002, to further mitigate the potential health hazards of DBPs.

In the spirit of Executive Order 13175, and consistent with EPA policy to promote communications between EPA and tribal governments, EPA specifically solicits additional comment on this proposed rule from tribal officials.

K. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 Fed. Reg. 28355 (May 22, 2001)), provides that agencies shall prepare and submit to the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, a Statement of Energy Effects for certain actions identified as "significant energy actions." Section 4(b) of Executive Order 13211 defines "significant energy actions" as "any action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) that is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action."

We have not prepared a Statement of Energy Effects for this final rule because this rule is not a significant energy action, as defined in Executive Order 13211. While this rule is a significant regulatory action under Executive Order 12866, it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

L. Likely effect of compliance with the Stage 2 DBPR on the technical, financial, and managerial capacity of public water systems

Section 1420(d)(3) of the SDWA as amended requires that, in promulgating a National Primary Drinking Water Regulations (NPDWR), the Administrator shall include an analysis of the likely effect of compliance with the regulation on the technical, financial, and managerial (TMF) capacity of public water systems. This analysis can be found in the Stage 2 DBPR EA (USEPA, 2001d).

Overall water system capacity is defined in EPA guidance (USEPA, 1998c) as the ability to plan for, achieve, and maintain compliance with applicable drinking water standards. Capacity has three components: technical, managerial, and financial. Technical capacity is the social and operational ability of a water system to meet SDWA requirements. Technical capacity refers to the physical infrastructure of the water system, including the adequacy of source water and the adequacy of treatment, storage, and distribution infrastructure. It also refers to the ability of system personnel to adequately operate and maintain the system and to otherwise implement requisite technical knowledge. Managerial capacity is the ability of a water system to conduct its affairs to achieve and maintain compliance with SDWA requirements. Managerial capacity refers to the system's institutional and administrative capabilities. Financial capacity is a water system's ability to acquire and manage sufficient financial resources to allow the system to achieve and maintain compliance with SDWA requirements.

The Stage 2 DBPR establishes three new requirements that may impact the TMF capacity of PWSs subject to the rule:

(1) Compliance with maximum contaminant levels (MCLs) established for total trihalomethanes (TTHMs) and for the sum of mono-, di-, and trichloroacetic acids, and mono- and dibromoacetic acids [the five haloacetic acids (HAA5)] based on a locational running annual average (LRAA). This requirement will be implemented in two distinct phases.

- Stage 2 A: MCLs of 120 Fg/L and 100 Fg/L for TTHMs and HAA5, respectively. Measured as LRAAs at the monitoring sites established under the Stage 1 DBPR.
- Stage 2 B: MCLs of 80 Fg/L and 60 Fg/L for TTHMs and HAA5, respectively. Measured as LRAAs at the monitoring sites identified as a result of the Initial Distribution System Evaluations (IDSEs) required under the Stage 2 DBPR (see below).

(2) Conducting an IDSE to identify the locations within a distribution system with the highest TTHM and HAA5 levels.

(3) Additional routine monitoring for disinfection byproducts.

In addition, personnel from systems regulated under the proposed Stage 2 DBPR will need to familiarize themselves with the rule and its requirements.

The proposed Stage 2 DBPR will apply to all community water systems (CWSs) and non-transient non-community water systems (NTNCWSs) that add a primary or residual disinfectant other than ultraviolet light (UV), or that deliver water that has been treated with such a disinfectant. Based on data from the *Water Industry Baseline Handbook* (Baseline Handbook), 40,406 CWSs and 7,986 NTNCWs – 48,392 systems in all – disinfect the water that they

provide. However, most systems will not need to install treatment to comply with the new requirements of the proposed rule. Please refer to Table VIII-3 for a complete listing of the requirements and a description of the type and number of systems affected by each requirement.

Table VIII.3. Number of systems subject to the requirements of the Stage 2 DBPR

Requirement	Affected Systems			
	Description	Number		
		CWSs	NTNCWSs	Total
Familiarization with the Stage 2 DBPR	All systems that disinfect	34,581	8,110	42,691
Adding treatment to comply with MCLs for TTHMs and HAA5 based on LRAAs – Stage 2 A and Stage 2 B	Systems with TTHMs $ 120 Fg/L and/or HAA5 $ 100 Fg/L; Systems with TTHMs $ 80.0 Fg/L and/or HAA5 $ 60.0 Fg/L	1,043	227	1,270
Conducting an IDSE	NTNCWSs serving 10,000 or more people and CWSs with TTHMs $ 40.0 Fg/L and/or HAA5 $ 30.0 Fg/L at any point over the preceding 2 years	9,803	11	9,814
Additional routine monitoring for DBPs	CWSs serving between 500 and 10,000 people	10,306	3	10,309

1. Quantitative analysis

The impact estimates presented in Table VIII.4 reflect the anticipated impact of the Stage 2 DBPR on system capacity based on the expected changes that systems will be required to adopt (e.g., selecting monitoring sites for the IDSE, installing/upgrading treatment, operator training, communication with regulators and the service community, etc.). A detailed qualitative description of the rationale behind the assigned scores is provided in the next section.

Table VIII.4. Estimated Impact of the Stage 2 DBPR on System Capacity (0 = no impact, 1 = minimal impact, and 5 = very significant impact)

Requirement	Technical Capacity			Managerial Capacity			Financial Capacity		
	Source Water Adequacy	Infrastructure Adequacy	Technical Knowledge & Implementation	Ownership Accountability	Staffing & Organization	Effective External Linkages	Revenue Sufficiency	Credit Worthiness	Fiscal Mgmt. & Controls
Familiarization w/ requirements of the rule	0	0	1	0	1	0	0	0	0
Compliance with MCLs for TTHMs & HAA5	2	4	3	0	2	3	5	5	3
Conducting IDSE (monitoring required)	0	0	2	1	0	2	2	0	1
Conducting IDSE (add'l monitoring not required)	0	0	1	1	0	1	0	0	0
Additional routine monitoring	0	0	1	0	0	0	1	0	0

2. Qualitative analysis

a. General

The purpose of this analysis is to identify the incremental impact that the Stage 2 DBPR will have on the TMF capacity of regulated water systems. Therefore, the baseline assumed for this analysis is complete implementation of the Stage 1 DBPR, IESWTR, and LT1ESWTR. As a result, it is anticipated that many of the systems facing the most difficult DBP challenges will have made appropriate modifications to their treatment process (e.g., changed point of disinfection, installed membrane technologies, etc.) to achieve compliance and therefore will not need to install additional treatment technology to achieve compliance with the Stage 2 DBPR. However, the revised methodology for measuring system compliance with the MCLs for TTHMs and HAA5 (i.e., LRAA) will require systems to reduce peak levels in DBP concentrations and 'hot spots' within the distribution systems of PWSs. Since LRAA represents a more stringent testing standard than RAA, it is likely that some systems that meet the requirements established by the Stage 1 DBPR will be required to make (further) changes to their treatment processes to comply with the Stage 2 DBPR. The impact of the requirement established by the more stringent (second) phase of rule implementation will be analyzed for the purpose of this analysis.

b. Familiarization with the Stage 2 DBPR

The requirements established under the Stage 2 DBPR are straight-forward (use of LRAA instead of RAA to determine compliance with the MCLs for DBPs) and are grounded in requirements previously established under the Stage 1 DBPR. As a result, it is not expected that regulated systems will face more than a minimal challenge to their technical and managerial capacity as a result of efforts to familiarize themselves with the Stage 2 DBPR.

c. Compliance with MCLs for total trihalomethanes and the five haloacetic acids

The impacts to the managerial capacity of systems affected by the revised DBP MCLs are not anticipated to be as great as the technical and financial challenges. However, system managers will need to review the implications of the revised method for measuring compliance with the MCLs for TTHMs and HAA5 and may need to hire a more highly certified operator or provide additional training for the existing operator to ensure that system staff can safely and effectively operate all new elements of the system's treatment train at all times. In addition, systems will need to rely on and improve upon their communication with regulators, technical and financial assistance providers, and their service community.

The impact of the Stage 2 DBPR on the financial capacity of regulated systems is closely tied to the Rule's impacts on technical capacity. Systems that must install additional treatment processes or upgrade their current treatment processes will face high costs. These costs may pose particular difficulty for many of the affected systems since the majority are relatively small (i.e., serving less than 3,300 customers), and therefore typically have a smaller revenue base and fewer households over which they may distribute the additional costs. Moreover, it is anticipated that some of these systems will elect to develop an alternative source (e.g., one with lower levels of naturally-occurring organic material) or interconnect with a nearby system if treatment costs prove prohibitive.

Therefore, on the basis of the TMF challenges posed by this requirement, it is anticipated that the implementation of the revised monitoring methodology will have a substantial impact on the capacity of the 1,043 CWSs and 227 NTNCWSs that are expected to make treatment changes to reduce DBP concentrations to comply with this rule.

d. Conducting an initial distribution system evaluation

This requirement was incorporated into the Stage 2 DBPR to ensure that the locations at which systems monitor for DBPs are sites at which TTHM and HAA5 values are highest. IDSEs are required of most PWSs under the Stage 2 DBPR. However, this requirement will not impact all systems that disinfect. Systems that possess monitoring data demonstrating that TTHM and HAA5 levels in their finished waters have been less than 40 Fg/L and 30 Fg/L, respectively, for at least the last 2 years will not need to conduct an IDSE. NTNCWSs that serve 10,000 or fewer people are exempt from this requirement. Furthermore, the IDSE requirement will not impact the capacity of all systems subject to the requirement to the same extent. Some systems will be able to meet this requirement without conducting extensive additional monitoring through a State waiver (for systems serving fewer than 500 people) or the submission of historical data that satisfies the regulatory agency that the systems are already monitoring for DBPs at appropriate locations. It is expected that large surface water systems will typically be required to conduct the greatest amount of monitoring for the IDSE, while small ground water systems will be required to conduct the least.

Prior to the implementation of an IDSE, those systems that must monitor will need to select locations at which they will conduct the necessary monitoring for DBPs. Despite knowledge gained as a result of implementing the Stage 1 DBPR, identifying appropriate sampling locations and getting buy-in on these locations from State regulatory agencies is expected to require a modest improvement in the technical and managerial capacity of many systems. In contrast, this requirement will have a much smaller impact on the capacity of those systems that do not have to monitor. While these systems may need to reinforce pre-existing

connections with regulatory agencies to enable effective and efficient communication with regulatory agencies, they will not be required to conduct as much new technical analysis of their distribution system and its impact on finished water quality. Regardless of whether or not a system must conduct new IDSE-specific monitoring, however, this requirement will have an impact on ownership accountability – all necessary data (new or historic) must be submitted to the appropriate regulatory agency.

The cost of sampling for DBPs may have a moderate impact on the financial capacity of some systems (especially small systems) since the analytical costs for the contaminants of concern are approximately $220 per sample. To meet these additional costs, in turn, may require some systems to revisit their current budgeting practices and fee structures.

e. Additional routine monitoring

It is anticipated that the additional routine monitoring required of some small systems (those serving between 500 and 10,000 people) will have a relatively limited impact on system capacity since only a limited number of additional samples will be required (four for surface water systems and one for groundwater systems on an annual basis) and since systems already have experience sampling for DBPs. Nonetheless, it is important to recognize that the costs for the necessary analyses may strain the financial capacity of some small systems.

f. Summary

The Stage 2 DBPR will have a potentially substantial impact on the capacity of the 1, CWSs and NTNCWSs that must make changes to their treatment process to achieve compliance with the MCLs for TTHMs and HAA5 on the basis of LRAA. However, while the impact to these systems is potentially significant, only 3.0 percent of all systems regulated under the Stage

2 DBPR (1,270 of 42,691) will be affected by this requirement. The new IDSE and monitoring requirements are expected to impact the capacity of an additional 9,814 systems to a small degree. 42,691 systems (i.e., 64.9 percent of regulated systems) are expected to experience minimal impact on their capacity as a result of the Stage 2 DBPR. Table VIII-5 provides information about the distribution of CWSs and NTNCWSs within each of the three impact categories for the Stage 2 DBPR.

Table VIII.5. Impact of the Stage 2 DBPR on CWS and NTNCWS capacity

Type of Water System	Impact on System Capacity*		
	Minimal Impact	Small Impact	Significant Impact
CWSs	13,429 (39%)	20,109 (58%)	1,043 (3%)
NTNCWSs	7,869 (97%)	14 (0%)	227 (3%)
Total	**21,298 (50%)**	**20,123 (47%)**	**1,270 (3%)**

Note: Totals may not add to 100 percent due to individual rounding.

[Small impact systems = those conducting an IDSE and those conducting additional routine monitoring from Table VIII.3. Minimal Impact systems = total systems minus the small impact systems minus the significant impact systems]

M. Plain language

Executive Order 12866 and the President's memorandum of June 1, 1998, require each agency to write its rules in plain language. EPA invites comments on how to make this proposed rule easier to understand. For example: Has EPA organized the material to suit commenters' needs? Are the requirements in the rule clearly stated? Does the rule contain technical language or jargon that is not clear? Would a different format (grouping and ordering of sections, use of headings, paragraphs) make the rule easier to understand? Could EPA improve clarity by adding tables, lists, or diagrams? What else could EPA do to make the rule easier to understand?

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